UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

In re: NEURONTIN MARKETING AND SALES PRACTICES LITIGATION	MDL Docket No. 1629 Master File No. 04-10981
THIS DOCUMENT RELATES TO: ALL CLASS ACTIONS	Judge Patti B. Saris
HARDEN MANUFACTURING CORPORATION: LOUISIANA HEALTH SERVICE INDEMNITY COMPANY, dba BLUECROSS/BLUESHIELD OF LOUISIANA; UNION OF OPERATING ENGINEERS, LOCAL NO. 68 WELFARE FUND; ASEA/AFSCME LOCAL 52 HEALTH BENEFITS TRUST; GERALD SMITH; and LORRAINE KOPA, on behalf of themselves and all others similarly situated, Plaintiffs, vs. PFIZER INC. and WARNER-LAMBERT COMPANY, Defendants.	

AMENDED CLASS ACTION COMPLAINT

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NATURE OF THE CASE

I. INTRODUCTION

1. This class action is brought by Plaintiffs Louisiana Health Service Indemnity Company dba BlueCross/BlueShield of Louisiana; Union of Operating Engineers, Local No. 68 Welfare Fund; ASEA/AFSCME Local 52 Health Benefits Trust; Harden Manufacturing Corporation; Gerald Smith; and Lorraine Kopa (collectively, "Plaintiffs"), on behalf of themselves and a class of similarly situated individuals and entities (the "Class") to recover billions of dollars they paid to Defendants as a result of Defendants' fraudulent scheme to market and sell the drug Neurontin® ("Neurontin") for a variety of uses for which it is not approved, or medically efficacious.

2. Defendant Pfizer, Inc. ("Pfizer") currently markets and sells Neurontin, a drug approved as adjunctive therapy in the treatment of partial seizures with and without secondary generalization in patients with epilepsy. Since May 2002, Neurontin has also been approved for the management of postherpetic neuralgia (pain resulting from shingles or herpes zoster) in adults. Prior to Pfizer's acquisition of Defendant Warner-Lambert Company ("Warner-Lambert") in 2000, Neurontin was marketed and sold by Parke-Davis, a division of Warner-Lambert.

3. This action arises out of the unlawful marketing of a prescription drug and Defendants' efforts to have thousands of doctors prescribe that drug for uses for which the drug was neither approved or effective. Pharmaceutical companies must apply to the United States Food and Drug Administration ("FDA") for approval to sell a new drug. When the FDA approves a drug product, it also approves the labeling that accompanies the drug; this labeling indicates the manner in which the product is to be used. Although physicians are free to

prescribe approved drugs as they see fit to treat any condition or symptom, pharmaceutical companies are prohibited against promoting drugs for uses outside of the approved labeling, commonly referred to as "off-label" uses.

4. Strict federal laws and regulations govern the promotion and marketing of drugs for off-label uses. Defendants, however, ran roughshod over these laws and regulations, which are designed to insure that physicians receive accurate, scientifically valid information regarding the effectiveness of a drug for a particular use. From 1994 to the present, Defendants created and implemented a fraudulent marketing and sales scheme that dramatically boosted sales of Neurontin and allowed Defendants to reap unlawful and unfair profits at the expense of healthcare insurers, physicians, consumers, and others. Using physicians and intermediary marketing firms, Defendants aggressively marketed and sold Neurontin for off-label uses – which ranged from treatment for anxiety to treatment for alcoholism – in spite of a dearth of scientific evidence suggesting that the drug was medically efficacious when so used. To carry out this scheme, Defendants employed one or more enterprises to make false and fraudulent representations and statements about Neurontin's effectiveness for these uses and paid numerous unlawful kickbacks in violation of state bribery laws, including, but not limited to the commercial bribery law of Parke-Davis's home state, New Jersey.

II. PARTIES

5. Plaintiff Louisiana Health Service Indemnity Company dba BlueCross/BlueShield of Louisiana ("BCBSLA") is a Louisiana corporation headquartered in Louisiana providing health care and prescription drug benefits to its members and insureds. Throughout the class period, BCBSLA has paid or reimbursed eligible beneficiaries' prescription drug benefits for Neurontin for off-label use and was injured by the conduct alleged herein.

6. Plaintiff International Union of Operating Engineers, Local No. 68 Welfare Fund ("Local 68") is a union welfare fund headquartered in New Jersey. Throughout the class period, Local 68 paid or reimbursed eligible fund participants' prescription drug benefits for Neurontin for off-label use and was injured by the conduct alleged herein.

7. Plaintiff ASEA/AFSCME Local 52 Health Benefits Trust ("ASEA") is a union trust fund that has provided medical and prescription drug benefits to employees of the State of Alaska since July 2001. Since its inception, ASEA has paid or reimbursed eligible trust participants' prescription drug benefits for Neurontin for off-label use and was injured by the conduct alleged herein.

8. Plaintiff Harden Manufacturing Corporation ("Harden") is an Alabama corporation headquartered in Alabama. Harden is a self-insured employer providing medical and prescription drug benefits for its employees. During the class period, Harden paid or reimbursed its employees' prescription drug benefits for Neurontin for off-label use and was injured by the conduct alleged herein.

9. Plaintiff Gerald Smith is an Indiana resident. He was prescribed and purchased Neurontin from in or about October 1999 until in or about February 2001 for the treatment of headaches and neuropathic pain, off-label uses for which Neurontin were and are not approved.

10. Plaintiff Lorraine Kopa is a Pennsylvania resident. She was prescribed and purchased Neurontin from in or about November 2003 until in or about April 2004 for the treatment of pain, an off-label use for which Neurontin was and is not approved.

11. Defendant Pfizer, Inc. is a Delaware corporation with its principal place of business at 235 East 42nd Street, New York, New York. Pfizer is principally engaged in the

manufacture and sale of pharmaceuticals and is one of the largest pharmaceutical companies in the United States.

12. Defendant Warner-Lambert Company was acquired in June 2000 by Pfizer. This acquisition included Warner-Lambert's Parke-Davis division. Prior to the acquisition, Warner-Lambert was a Delaware corporation that maintained its principal place of business at 201 Tabor Road, Morris Plains, New Jersey. In 1993, Warner-Lambert received FDA approval to market Neurontin in the United States and did so through its Parke-Davis division. After the acquisition, the marketing of Neurontin continued to be managed at the merged-out companies' Morris Plains, New Jersey location.

III. JURISDICTION AND VENUE

13. This Court has subject matter jurisdiction pursuant to 28 U.S.C. § 1331, because this action arises under the laws of the United States, and 28 U.S.C. § 1964(c), because this action alleges violations of the Racketeer Influenced and Corrupt Organizations Act ("RICO"), 18 U.S.C. § 1962.

14. This Court has supplemental jurisdiction pursuant to 28 U.S.C. § 1367 over the violations of the New Jersey Consumer Fraud Act and Plaintiffs' allegations of common law fraud and unjust enrichment.

15. Venue is proper in this judicial district pursuant to 28 U.S.C. § 1391(b) and (c), and 18 U.S.C. § 1965.

IV. FACTUAL ALLEGATIONS

A. Neurontin

16. Defendants are the manufacturers and distributors of Neurontin, a prescription drug. Neurontin is the brand name of the chemical compound (1-aminomethyl)-1-

cyclohexaneacetic acid, generically known as gabapentin. Until 2004, Defendants were the exclusive providers of Neurontin in the United States.

17. In December 1993, the FDA approved Neurontin for "adjunctive therapy" in the treatment of partial seizures with and without secondary generalization in adults with epilepsy. "Adjunctive therapy" means that the drug cannot be prescribed by itself for the treatment of epilepsy—it is to be used in combination with another "front line" epilepsy drug. The FDA did not find Neurontin to be safe and effective as a "monotherapy"—a single drug treatment for epilepsy. The FDA approved labeling of Neurontin states that the drug is only effective at doses ranging from 900 to 1800 mg/day. On May 24, 2002, the FDA also approved Neurontin for the management of postherpetic neuralgia, which is pain resulting from nerve damage caused by shingles.

18. In 1995, a Neurontin regimen within the FDA-approved daily dose range of 900 mg to 1800 mg cost between $2.25 and $4.50 per day, or between $68.50 and $137.00 a month. A year's supply of Neurontin could cost between $800 and $1,600. Defendants held a monopoly on the production of Neurontin through 2004, and the price for treatment has increased between 1995 and the present day.

B. Parke-Davis's Deliberate Decision to Avoid FDA Approval and Market Neurontin Off-Label

19. Parke-Davis knew that the market potential for Neurontin for its approved use as adjunctive therapy for partial seizures was modest. In May 1994, it estimated that Neurontin's ultimate sales potential was $500 million over the lifetime of the drug, based on Neurontin's narrow use for epilepsy.

20. Parke-Davis also knew, however, that Neurontin had other potential uses besides epilepsy. In the late 1980s and early 1990s, before the FDA approved Neurontin for

epilepsy adjunctive therapy, Defendants filed several patent applications for Neurontin as a treatment for depression, neurodegenerative disease, mania, bipolar disease and anxiety. Notwithstanding the claims made in the patent applications, Parke-Davis did not seek FDA approval for these indications or start the internal process within Parke-Davis to obtain approval for these uses. Neurontin's short U.S. patent life was a major factor in this analysis. The patent was set to expire in a few years, leaving Parke-Davis with only a small window of exclusivity for this drug during which it could reap monopolistic profits from its sale. After the expiration of the Neurontin patent, Defendants would be forced to share the market for Neurontin with generic drug manufacturers, substantially reducing their profits and their ability to keep Neurontin's retail price high. Senior product managers viewed Neurontin as a niche drug and advised the corporation to move off big numbers regarding the ultimate sales potential for Neurontin.

21. In October 1994, the Neurontin Development Team, a group of high-level officials who examined regulatory, clinical research, patents, marketing and manufacturing issues regarding Neurontin, began to consider whether Parke-Davis should attempt to extend Neurontin's use to psychiatric disorders. The principal reason for extending the use was because other anticonvulsants were used for (and FDA-approved for) psychiatric disorders, such as bipolar disorder, panic disorder, post-traumatic stress disorder and possibly personality disorders.

22. Notwithstanding other anti-epileptic drugs being used for psychiatric disorders, Parke-Davis knew there was no scientific rationale for Neurontin being effective for bipolar disorder, acute mania, social phobia and panic disorder because Neurontin has a different mechanism of action than other anti-epileptics.

23. In January 1995, Parke-Davis's Marketing and Planning department, presented a preliminary market analysis to the Neurontin Development Team regarding

Neurontin's potential use for psychiatric indications. Without considering whether the drug was actually effective for such uses, or how Parke-Davis could prove the drug worked for these conditions, the report viewed the market as very favorable for Neurontin. At the same Neurontin Development Team meeting, the possibility of expanding Neurontin's use for pain syndromes, another market substantially larger than epilepsy, was also discussed.

24. In February 1995, the New Product Committee ("NPC") informed the Neurontin Development Team that it supported the development of Neurontin for other indications and asked for a formal proposal. John Boris was instructed to prepare market feasibility analyses of new potential indications, including bipolar disorder, generalized anxiety disorder and social phobia, neuropathic pain and migraine prophylaxis.

25. In March 1995, a senior scientist in Parke-Davis's Research Department informed the Neurontin Development Team that it would not be a good use of Parke-Davis resources to obtain regulatory approval for using Neurontin to treat bipolar disorder because of the short patent exclusivity period remaining and because the clinical studies needed to prove that the drug actually worked for this indication would be hard to conduct and expensive. The Development Team, however, was informed that a "publication study will be less expensive and focus on what management organization and clinician want to know." Members of Parke-Davis' Regulatory Department opposed the pursuit of a "publication strategy," stating that seeking FDA approval for bipolar disorder through appropriate clinical studies was the correct way to proceed. That recommendation was not followed.

26. On March 22, 1995, the Parke-Davis Marketing Council, meeting in Lyons, France, recommended that Parke-Davis pursue a "publication strategy" instead of formal regulatory approval with regard to psychiatric indications for Neurontin in the United States

because "the patent situation would most likely not allow Parke-Davis to optimize the investment required to obtain a full indication." Members of the Marketing Council included Tony Wild, the President of Parke-Davis, and senior management.

27. The object of a "publication strategy" was to disseminate information as widely as possible through the world's medical literature. Parke-Davis recognized that publishing Neurontin's studies on off-label uses would increase sales. Parke-Davis estimated that performing clinical trials sufficient to obtain FDA approval would be at least three times the cost of pursuing a publication strategy and that double blind clinical studies were unnecessary to publicize Neurontin's utility for psychiatric uses.

28. In May 1995, a formal Marketing Assessment recommended that Parke-Davis implement a publication strategy for various psychiatric indications. The report predicted that the revenues generated by sales for these indications would justify investment in the publication strategy. The report, however, specifically noted a lack of scientific rationale for Neurontin's use for bipolar disorder, since Neurontin has a different mechanism of action than other anti-epileptics. Other Parke-Davis reports had recognized that the rationales for using Neurontin for acute mania, social phobia and panic disorder were essentially the same as the rationale for using Neurontin to treat bipolar disorder.

29. In July 1995, Parke-Davis Marketing and Planning department issued a final Marketing Assessment on Neuropathic Pain and Spasticity. That report recommended that Parke-Davis pursue a publication strategy in the areas of neuropathic pain associated with peripheral nerve damage due to diabetes mellitus, trigeminal neuralgia, postherpetic pain, neuropathic facial pain, and reflex sympathetic dystrophy, disseminating information about such uses through publication and key neurological and pain congresses. Parke-Davis management

approved these marketing assessments and adopted the recommendations regarding the publication strategy. In approving the publication strategy for Neurontin, however, Parke-Davis only intended to publish studies that generated positive results.

30. The New Product Committee also approved the decision to conduct publication studies for Neurontin in migraine prophylaxis but restricted publication to only positive study results. In fact, the negative results of a clinical trial conducted in the 1980s relating to Neurontin and migraine have never been published.

31. Thus, by late 1995, senior management at Parke-Davis had committed the company to promoting Neurontin for off-label uses for which it had no intention of ever seeking FDA approval, including bipolar disorder, generalized anxiety disorder, social phobia, migraine, trigeminal neuralgia, postherpetic pain, neuropathic facial pain, and reflex sympathetic dystrophy. No clinical trial suggested that Neurontin was effective for any of these conditions and at least one clinical trial demonstrated that Neurontin was not effective for at least one of these conditions. Moreover, because FDA regulations prohibited Parke-Davis employees from promoting Neurontin for off-label uses, these marketing decisions required Parke-Davis to construct a marketing organization that appeared to be separate and independent from Parke-Davis's existing marketing and sales department. These marketing decisions required the creation of a new enterprise, or several enterprises, of third parties that would market Neurontin to physicians for off-label uses. As will be demonstrated below, in order to distance Parke-Davis from the off-label promotion and hide the absence of clinical data in support of these off-label uses, the marketing enterprises Parke-Davis conducted routinely engaged in acts of mail fraud, wire fraud, commercial bribery, unfair and deceptive trade practices and other unlawful conduct.

C. Regulation of Defendants' Marketing Practices and Restrictions on Promotion of "Off-Label" Uses for Prescription Drugs

32. The FDA closely regulates the marketing and promotion of prescription drugs. Under the Food Drug and Cosmetic Act, and the regulations promulgated thereunder, all information provided by a drug company about its products, whether on or off-label, whether directed at consumer or physicians, must be fair and balanced. To be fair and balanced, information about a drug company's products must accurately and fairly present all data relevant to any drug information provided. In practice, this mean a drug company must present positive as well as negative information known to a drug company about its products. Drug companies may not present half-truths or disclose select information favorable to their position. In order to meet their obligation of providing fair and balanced information, drug companies must make full disclosure. Parke-Davis was aware of these requirements and routinely trained its marketing personnel that they had to present all negative information along with any positive information.

33. At all times relevant hereto, Defendants' promotion of their products for off-label uses was also closely regulated. The general rule was that drug companies could only promote their products for uses that had been approved by the FDA. Sales personnel could not discuss off-label uses with physicians during sales visits, and off-label uses were not supposed to be discussed in any promotional event sponsored by Defendants.

34. The FDA did, however, issue guidelines that allowed Defendants to provide information concerning off-label uses in very limited circumstances. These included:

35. Defendants could provide an unrestricted grant to an accredited independent sponsor of continuing medical education programs, provided Defendants did not influence the content of the program. Thus, Defendants could not select the topics to be

presented at such programs or approve the speakers or the content to be provided. Only programs that were truly independent of the drug companies were supposed to qualify for this exception.

36. Defendants could provide off-label information to bona-fide medical consultants provided the actual purpose of the consultation was to have the persons retained provide information to Defendants.

37. Defendants were also permitted to communicate off-label information to physicians in response to a bona fide, unsolicited request from a physician, provided such information was specifically responsive to the physician's request.

38. As noted above, when Defendants were permitted to provide off-label information, all information was required to be fair and balanced. Fair balance was not limited to written materials but all presentations.

39. In response to unsolicited requests from physicians, a drug company could provide copies of published articles about off-label usage (provided such materials were responsive to the request and the presentation was fair and balanced). The Defendants' publication strategy depended upon the existence of such articles in order to publicize Neurontin's "emerging uses", a euphemism for "off-label" uses. However, because Defendants had not conducted any clinical trials relating to the off-label uses (except for the one trial which results the Defendants suppressed), they needed to create articles and to attract physicians who would use Neurontin for unapproved uses and then publicize those results.

40. Subsequent to the marketing assessments described above, Parke-Davis's marketing department budgeted millions of dollars to be paid to physicians for "studies" of off-label uses of Neurontin. These "studies" ranged from paying physicians to describe their off-label Neurontin usage to technical writers who would then write case reports under the

physicians' names, to substantial subsidies for plans to use Neurontin experimentally on patients. Pursuant to the publication strategy described above, only favorable results would be published and physicians were made to understand that continued funding would only occur if there were favorable results. Many of these studies were not double-blind and most of the studies had negligible scientific or research value. This initiative, however, resulted in the creation of a wealth of off-label articles Parke-Davis could circulate.

41. Regulation of off-label promotion also restricted the means by which Parke-Davis could publicize information about off-label usage. It could not use its sales force to inform doctors of Neurontin's alleged ability to treat pain or psychiatric conditions, as it normally would when publicizing a new approved pharmaceutical. It had to create parallel marketing structures that appeared independent from Parke-Davis's ordinary promotion forces. Thus, to institute the off-label marketing plan, Parke-Davis had to create an enterprise--an association in fact consisting of physician advocates and vendor organizations-- that would publicize Neurontin for off-label purposes, but make it appear that Parke-Davis did not have control of the content of the messages being distributed. The enterprise (or enterprises) that Parke-Davis ultimately created relied upon false representations delivered by mail and wire, and commercial bribery to accomplish their goal of dramatically increasing Neurontin use in the United States.

42. Parke-Davis's inability to use its usual sales force to promote unapproved uses of Neurontin presented one advantageous opportunity. Parke-Davis was aware that physicians view promotional presentations by drug companies with caution, and are generally skeptical of representations made by drug company salespersons. However, it also knew that recommendations by fellow practitioners, particularly respected practitioners, were highly

regarded by most physicians and were particularly effective in getting doctors to change prescription behavior. Consequently, Parke-Davis deliberately decided to market Neurontin off-label through "peer-selling." Doctors would be trained to sell Neurontin to other doctors in the guise of educational or professional programs. This marketing strategy, however, could only succeed if it appeared that the doctor-spokespersons were promoting off-label Neurontin because they had independently determined that such treatment was beneficial for their patients, not because they were actually the mouthpieces of a drug company marketing plan. Throughout its off-label promotion campaign Defendants hid their involvement in the promotion of off-label information and mislead physicians into believing that the physicians who promoted Neurontin were independent or not otherwise part of the enterprise Parke-Davis created to market Neurontin off-label.

D. The Off-Label Promotion Enterprise

43. Parke-Davis established the Off-Label Promotion Enterprise to accomplish two goals that were instrumental to its scheme to market Neurontin for off-label indications. First, it had to create parallel marketing structures that appeared independent from Parke-Davis's ordinary promotion forces to avoid federal regulations concerning off-label promotion. Second, to execute the publication strategy, favorable articles had to be generated and published that appeared to emanate from independent physicians. These two goals were complementary and mutually reinforcing. The production of favorable publications created a "buzz" regarding Neurontin, while the peer-to-peer marketing and promotion allowed aggressive sales pitches to continue with a veneer of legitimacy. To achieve these goals, two sub-enterprises were established: the Peer Selling Sub-Enterprise (described below) and the Publication Sub-Enterprise (described below).

1. Peer Selling Sub-Enterprise

44. Defendants' peer-to-peer marketing scheme centered on hosting numerous events where doctors trained and/or approved by Parke-Davis would provide favorable information on the off-label use of Neurontin, often under conditions where physicians would be compensated for attending the presentation. Defendants funded hundreds of such events between 1996 and 2003. As noted above, Parke-Davis was prohibited from directly producing such events, so it created and controlled a Peer Selling Sub-Enterprise composed of medical marketing firms (the "vendor participants") and several dozen physicians (the "physician participants") who routinely promoted Neurontin to other physicians in venues all across the country. Defendants maintained sufficient control over the enterprise to select and approve the content of the programs and the physician participants that would deliver the off-label message. The physicians who attended these events were deceived into thinking that the events were educational in nature and independent from the control of the Defendants.

45. In order to hide the lack of scientific support for the off-label uses promoted by the Enterprise, and Defendants' direct involvement in Neurontin's off-label promotion, the Enterprise had no choice but to employ improper and unlawful sales and marketing practices. These practices included, inter alia: (a) deliberately misrepresenting the safety and medical efficacy of Neurontin for a variety of off-label uses; (b) knowingly misrepresenting the existence and findings of scientific data, studies, reports and clinical trials concerning the safety and medical efficacy of Neurontin for a variety of off-label uses; (c) deliberately concealing negative findings or the absence of positive findings relating to Neurontin's off-label uses; (d) misrepresenting the credentials and qualifications of certain of Defendants' employees as specialists, medical researchers, physicians and scientific employees in order to market and sell Neurontin for various off-label uses; (e) wrongfully and illegally

compensating physicians for prescribing Neurontin for various off-label uses; (f) knowingly publishing articles, studies and reports misrepresenting the scientific credibility of data and touting the medical efficacy of Neurontin for off-label uses; (i) intentionally misrepresenting and concealing Defendants' role and participation in the creation and sponsorship of a variety of events, articles and publications used to sell Neurontin to off-label markets; and (j) intentionally misrepresenting and concealing the financial ties between the Defendants and other participants in the Enterprise.

46. Defendants' scheme reaped them significant financial gain. From 1995 to 2003, Defendants' revenues from the sale of Neurontin soared from $97.5 million to nearly $2.7 billion. By 2003, 90% of all Neurontin prescriptions were for off-label uses, compared with 50% in 1996. Sales of the drug have grown at a rate of 50% per year, fueled primarily by prescriptions for off-label uses.

47. All of the participants in the Peer Selling Sub-Enterprise associated with the Defendants with the common purpose of aiding them in marketing Neurontin for off-label uses and to achieve "market expansion" of these uses. Each of the participants received substantial revenue from the scheme to promote Neurontin off-label. The more successful these marketing events were, the more events there would be in the future and the more fees each of the participants would receive for participating in the events. For these reasons, all of the participants knowingly and willingly agreed to assist Defendants in their off-label promotion of Neurontin, notwithstanding the fact that such a promotional campaign required the systematic repetition of false and misleading statements to, and the commercial bribery (through kickbacks) of, thousands of physicians throughout the United States, and the promotion of Neurontin for off-label indications by the Defendants was illegal.

48. Parke-Davis, and subsequent to Warner-Lambert's merger with Pfizer, Pfizer, controlled the Peer Selling Sub-Enterprise. Defendants compensated the other participants for all of their efforts on behalf of the Sub-Enterprise, and controlled the money flow to the participating vendors and physicians. As described below, on the rare occasions where members of the Peer-Selling Sub-Enterprise made statements that failed to support off-label use of Neurontin, Parke-Davis could and would cease the flow of funds to the offending participant. Parke-Davis closely monitored all events to insure the expected representations related to off-label Neurontin were made to physicians attending the events.

49. The Parke-Davis Neurontin Extended Disease Team, a formal team created by the Parke-Davis marketing department that included members of the Parke-Davis marketing department and at least one outside vendor, Cline, Davis & Mann, oversaw the execution of the Enterprise's operations. As described herein, Defendants have also controlled the content of the presentations, speeches, promotional events and articles that describe off-label usage of Neurontin.

a. The Role of Medical Marketing Firms

50. Third party medical marketing firms were critical to Parke-Davis's scheme to promote off-label from the scheme's inception. Parke-Davis's marketing plans called for off-label information concerning Neurontin to be widely disclosed in continuing medical education programs, "consultants' meetings", and other programs where physicians could instruct other doctors how to use Neurontin for unapproved indications. Bona fide continuing medical education programs, and similar educational events were exempt from FDA rules prohibiting off-label promotion because the sponsoring organization—which was often a non-profit, like a medical school, was independent and was supposed to control the programs' content. In practice, however, these programs were produced with the assistance of third party

medical marketing firms. These firms handled the logistics of setting up and running the events, including transporting the presenting physicians to the event, attracting doctors to attend the event and handling all financial transactions. The vendors, however, were not supposed to supply content or control the selection of presenting physicians.

51. Parke-Davis's marketing strategies turned the proper practices for presenting continuing medical education programs on their head. Instead, of accredited institutions planning independent programs and then approaching third party vendors and financial sponsors, Defendants intended to create turnkey medical programs, with financing already included, and then find "independent" institutions that would present the package in the format the Defendants and the Off-Label Enterprise created.

52. Defendants' Publication Strategy required Defendants to work with the participating vendors to design the events that would promote off-label Neurontin. The specific plans drafted to execute the Publication Strategy were called "tactical plans." Parke-Davis drafted tactical plans, and tactical plans were also drafted by participating vendors such as Cline, Davis & Mann and Physicians World, particularly when representatives of those entities sat on the Neurontin Extended Disease Team, a team within Parke-Davis that oversaw the execution of the Publication Strategy.

53. The tactical plans called for participating vendors to produce, and Defendants to pay for, hundreds of events, including medical education seminars, "consultants' meetings", advisory boards, speakers' bureaus, teleconferences and dinner meetings, where the physician members of the Peer Selling Sub-Enterprise would promote the off-label use of Neurontin to thousands of doctors who had no intention of prescribing Neurontin for adjunct epilepsy treatment. Once Defendants and the participating vendors had worked together to

determine the content of a particular program or series of programs, the participating vendors would submit a proposal to Parke-Davis to fund these programs. The grant covered all expenses of producing programs including the participating vendors' fee and expenses, the speaking fees and travel expenses of the participating doctors, payments to the accrediting institutions (in the case of medical education events), costs incurred in hosting and producing the event, honorarium to be paid to the attending physicians, and in some cases, the attendees' travel, lodging, food and entertainment expenses. At each medical education event, the participating vendors and Defendants claimed that the events were sponsored by an "unrestricted" grant from the Defendants. However, there was nothing "unrestricted" about the money Defendants paid. Pursuant to Defendants' marketing strategies and the tactical plans created by the Defendants and the participating vendors, the funds were expressly provided for the purpose of obtaining a program that extolled the use of Neurontin for unapproved indications.

54. Pursuant to the tactical plans the participating vendors worked out with the Defendants, the participating vendors solicited the accrediting institutions to present the medical education programs they had designed with the Defendants. The participating vendors submitted detailed proposals for these events, informing the accrediting institutions that the events would be presented without any financial risk or expense to the accrediting institutions. The accrediting institutions only needed to place their imprimatur (and certification) on the planned programs and receive the payments included in the proposals. The resulting event was not an independent medical education seminar designed by an accredited medical education provider, but a promotional program designed by the Peer Selling Sub-Enterprise that delivered the message defined in Defendants' marketing strategies and tactical plans—that Neurontin could and should be prescribed for unapproved uses.

55. Another method used to illegally promote Neurontin for off-label uses was through "Consultants' Meetings" and advisory board meetings coordinated and produced by the participating vendors. Prior to its off-label marketing campaign for Neurontin, Parke-Davis occasionally held advisory committee meetings and consultants' meetings for the purpose of getting independent advice from experts regarding particular aspects of their existing or planned drug products. When such events involved only a limited number of invitees and Parke-Davis was legitimately seeking expert advice, such small-scale events could properly include discussion of off-label usage. Parke-Davis and the participating vendors exploited this loophole by hosting numerous events, which they called advisory board or consultants' meetings, but where Parke-Davis did not actually seek advice or consultation from the attendees. The real purpose of these events was to expose the attendees to Neurontin's uses for non-epilepsy treatment. These meetings were frequently held at luxury resorts and the attendees' travel, room and board were paid for by Parke-Davis.

56. The vendor participants knew the events they coordinated and produced were designed to qualify for recognized exceptions to the FDA's off-label marketing rules, and knew that the programs neither met the criteria for the exceptions nor provided legitimate independent medical education to the physicians. The participating vendors also knew that the programs did not provide fair and balanced drug information to the attendee physicians. In fact, the vendor participants (with the assistance of the participating physicians and the Defendants) intentionally designed the programs so that the attendee physicians would not receive fair and balanced information. The participating physicians knew that failure to provide fair and balanced information meant the information the attending physicians received would be false and misleading because vital information necessary to evaluate Neurontin's efficacy was

intentionally suppressed. Among the information the Defendants, the participating vendors and the participating physicians deliberately omitted from the events they sponsored was the following:

- the lack of clinical trial evidence to support Neurontin's off-label uses;
- negative clinical trial results that demonstrated that Neurontin was no more effective than a placebo for several off-label conditions;
- negative anecdotal evidence that Neurontin did not work for off-label conditions;
- information that virtually all publications and studies that allegedly supported Neurontin's off-label use had been funded by Defendants;
- information that virtually all publications and studies that allegedly supported Neurontin's off-label use had been initiated by Defendants pursuant to a corporate marketing plan designed to increase off-label sales;
- information that no scientific evidence explained Neurontin's mechanism of action, which in turn meant there was no scientific explanation regarding why Neurontin might work for the off-labels for which it was being promoted;
- information that Parke-Davis had deliberately decided not to publish or publicize any studies that found that Neurontin was not effective for off-label uses;
- information that the participating doctors who were conducting the peer selling had been paid substantial subsidies to use Neurontin on their patients for off-label purposes;
- that the events the physicians were attending were neither fair or balanced and were created to insure the physicians would not hear a fair and balanced examination of Neurontin for off-label uses; and

- information that the events were not funded, as advertised, by an "unrestricted" grant from the Defendants, but that the grants were conditioned upon the participating vendors and sponsoring institutions putting on presentations that painted off-label use of Neurontin in the most favorable light.

57. Each of the participating vendors was in regular communication with the Defendants. In connection with major medical congresses or conventions of the specialists that were the target of the off-label promotion campaign, the participating vendors coordinated their events to insure their off-label message reached the most physicians in the most effective manner. All of the participating vendors were also in regular communication with the participating physicians, and individual participating physicians would give the same presentation (or a substantially equivalent presentation) at different participating vendors' events.

58. The planning and coordination of all of these events by the third party medical marketing firms required extensive use of the wires and mails, including the mailing of invitations to physicians, the mailing of proposals to the accrediting institutions, booking of hotels and airplane tickets, the arrangement of meals, the scheduling of teleconference calls, the development and modification of the tactical plans, and the coordination of the content of the presentations on Neurontin to be presented at the event.

59. Firms that participated in the Peer Selling Sub-Enterprise included Cline, Davis & Mann (and its Proworx division), Physicians World (and its Professional Postgraduate Services division), Sudler & Hennessey (and its Intramed division), MEDED, Medical Educational Services ("MES"), CME, Inc., Boron LaPore and AMM/Adelphi. What follows is a brief description of the activities currently known to Plaintiffs that each of these third party medical marketing companies took on behalf of the Peer Selling Sub-Enterprise. However,

Plaintiffs' knowledge of these activities is very limited. Plaintiffs have only had the opportunity to review limited records, mostly of events between 1994 and 1998 that were held for the North East Customer Business Unit ("CBU"). Yet Plaintiffs are aware that similar events were held across the country and that such events did not cease until Pfizer signed a Corporate Integrity Agreement with the United States and various states in 2004 Plaintiffs have not seen records of the vast majority of such events and cannot specify them because the records are in the custody of Defendants or the other members of the Peer Selling Sub-Enterprise.

(1) Cline Davis

60. Cline, Davis & Mann, Inc. ("Cline Davis"), is a midtown Manhattan advertising and marketing firm, which caters to the pharmaceutical industry. Beginning in either late 1995 or early 1996, Cline Davis provided, and continues to provide, the Defendants with strategic management services, including advising Defendants on strategies and tactics to expand the on-label and off-label use of Neurontin. To this day, Cline Davis directs the advertising campaigns for various Pfizer products, including Neurontin and Viagra. Through its Proworx division, Cline Davis also managed and coordinated various marketing events, including "consultants'" meetings and other peer-to-peer sales marketing events.

61. Cline Davis shared costs associated with the off-label marketing of Neurontin with the Defendants. For example, when Cline Davis exceeded the budgeted amounts under its strategic management services for Neurontin in 1996, Parke-Davis agreed to split the budget overrun "in the spirit of partnership and a commitment to a long term relationship." The sharing of costs is evidence that the relationship between Cline Davis and the Defendants were partners in an enterprise, not principal and agent.

62. Cline Davis and the Defendants maintained systematic linkages between themselves, including continuing coordination between their respective marketing teams. For

example, at all relevant times hereto, a Cline Davis employee was a sitting member of the Parke-Davis's Extended Neurontin Disease Team, which was a high-level, confidential, internal interdisciplinary group composed of members from the following departments: Strategic Planning/Information Management, Neurontin Marketing, Advertising and Promotion, Product Planning, Medical Affairs, Forecasting, Training and Development, Healthcare Management, Public Relations, as well as representatives of Parke-Davis's five regional offices (which were called Customer Business Units or "CBUs").

63. Parke-Davis's control of the content of events produced by Cline Davis (and the other participating vendors) was best illustrated at a continuing medical education symposium coordinated by Cline Davis on behalf of American Diabetes Association, held in Boston, MA on June 23, 1997. At the eleventh hour, Cline Davis and Parke-Davis realized that one of the speakers, who had previously been recommended by Parke-Davis, would describe negative results in her study of Neurontin's use for an off-label indication. Unable to cancel the presentation without grossly violating the rules for conducting accredited continuing medical education seminars, Cline Davis, in its own words, took steps "to counteract a possible 'negative' presentation." Cline Davis planted a doctor in the audience to ask questions that would lead the presenter to make favorable statements during the question and answer period after her talk. According to Cline Davis's own words, this plant "did indeed lead Dr. Bril to address some of the positive aspects of anticonvulsants and Neurontin." In a memorandum written a day after the event, Cline Davis acknowledged its responsibility for allowing a presentation by a physician with an independent view, reaffirmed its "policy to complete a literature search to determine who authors favorable articles on the topics outlined" and assured

Parke-Davis that "guidelines have been to set to ensure that this type of situation [a negative presentation] does not happen again."

64. There existed between Cline Davis and the Defendants a common communication network for sharing information on a regular basis. Cline Davis and the Defendants routinely exchanged letters, memoranda, emails and phone calls. There were also regular meetings, including "face-to-face" meetings with the high-level marketing officials on both sides, at which overall goals and strategies were discussed. There were also more frequent, lower-level "Toolbox" meetings, where individual strategies and tactics would be discussed and progress in various areas of the off-label marketing scheme would be monitored.

65. Some, but not all, of the events Cline Davis presented on behalf of the Off-Label Promotion Enterprise included:

Neurontin Consultants Meeting	April 19-21, 1996	Jupiter Beach, FL
Neurontin Consultants Meeting	May 3 – 4, 1996	Philadelphia, PA
Neurontin Consultants Meeting	May 10 – 11,1996	Boston, MA

(2) Thompson Physicians World

66. Thompson Physicians World ("Physicians World") is a New Jersey based marketing and medical education firm, which caters to the pharmaceutical and healthcare industries. Physicians World managed and coordinated various marketing events, including speakers' bureau meetings, advisory boards and other peer-to-peer marketing events.

67. Through its wholly owned and wholly controlled Professional Postgraduate Services ("PPS") division, Physicians World also managed and coordinated various medical educational events. PPS purported to be an ACCME-accredited sponsor of CME events.

68. Like Cline Davis, Physicians World was actively engaged in advising Parke-Davis on strategies and tactics to expand the on-label and off-label use of Neurontin.

69. On December 22, 1995, at about the same time that Defendants formed their partnership with Cline Davis, Larry Perlow, Parke-Davis's vice-president of Portfolio Management, announced in a memorandum that Parke-Davis and Physicians World formed a "strategic partnership" to handle speakers bureaus, advisory boards, and consultants' meetings. The memorandum indicates that services formerly handled internally by Parke-Davis's Marketing Support Services would now by divided between Physicians World and Parke-Davis's Marketing Logistics department. Under the strategic partnership, speakers' bureau meetings, advisory boards, and consultants' meetings would be arranged by Physicians World; non-speaker medical education programs, grants and processing of all checks against advertising and promotion and departmental budgets would be handled by Marketing Logistics.

70. The same December 22, 1995 memorandum also announced that Parke-Davis and Physicians World would commingle employees. On or about January 1, 1996, Parke-Davis's Marketing Support staff joined Physicians World as full-time employees. Even though these employees were now based out of Physician World's Secaucus, New Jersey office, these employees continued to use the same toll free ("800") numbers that they used at Parke-Davis, continued to use Parke-Davis letter head, and provided the same services to Parke-Davis employees who contacted them.

71. In order to clarify marketing responsibilities in the wake of the strategic partnership and employee reassignment, Physicians World created various grids, which were circulated to marketing and sales colleagues in Parke-Davis and adopted as Parke-Davis policy. These grids explain the procedures for Parke-Davis and Physicians World to follow depending on whether the event fell under Physicians Worlds jurisdiction or remained under Marketing Logistics.

72. The use of these grids by both Parke-Davis and Physicians World, as well as the sharing of the toll free (800) numbers by the employees reassigned from Physicians World to Parke-Davis, and the continued use by the reassigned employees of Parke-Davis letterhead, constitutes evidence of continuing coordination and overlap of leadership functions, as well as the establishment of a joint communications network.

73. According to the coordination policies jointly developed by Parke-Davis and Physicians World, if an event were non-promotional, i.e. a CME, then the "accredited institution" — not Parke-Davis and Physicians World — was supposed to pick the speakers and the content of the presentations. However, the presentations were supposed to be fair and balanced, and were not supposed to pitch one drug product over another. When events were promotional, Parke-Davis and Physicians World were allowed to be "actively involved in speaker identification, recruitment as well as assistance with program content." However, the presentations of these handpicked speakers were supposed to be "strictly limited to approved indications."

74. In practice, Physicians World and Parke-Davis actively, knowingly, and with full support of the other, circumvented or directly violated both of the above policies. In fact, the distinction between promotional and education events was rendered meaningless since Physicians World owned and controlled PPS, which was the "accredited institution" for Physicians World's CME events. Regardless of the nature of the event, Physicians World selected physician-speakers and attendees, and controlled the content. Among the off-label programs Physicians World marketed where Parke-Davis controlled the content were an accredited home study program on pain, which they planned to circulate to 10,500 neurologists and pain doctors, and also "educational" programs on Neurontin's use for psychiatric conditions.

In both cases the accrediting institution, which was supposed to be independent, was Physicians World's subsidiary, PPS.

75. Physicians World also coordinated numerous "Consultants' Meetings" and advisory board meetings where off-label usage was extensively discussed. Some, but not all, of the events Physicians World presented on behalf of the Off-Label Promotion Enterprise included:

Physicians World Events

Title	Date	Location
Gabapentin Advisory Board: Evaluating Clinical Applications in Pain	September 1995	Boston, MA
Pain Management Study Group Meeting at the Mark Hopkins Intercontinental Hotel	May 29, 1996	San Francisco, CA
Pain Management Study Group Meeting at the Hotel Nikko	May 29, 1996	Los Angeles, CA
Pain Management Study Group Meeting at the Riverplace Hotel	May 30, 1996	Portland, OR
Pain Management Study Group Meeting at the Loews Santa Monica	May 30, 1996	Los Angeles, CA
Pain Management Study Group Meeting at the Red Lion Hotel	June 4, 1996	Sacramento, CA
Pain Management Study Group Meeting at the Madison Renaissance	June 5, 1996	Seattle, WA
Pain Management Study Group Meeting at the Hyatt Regency La Jolla	June 5, 1996	La Jolla, CA
Pain Management Study Group Meeting at the Oakland Memorial Center	June 6, 1996	Oakland, CA
Pain Management Study Group Meeting at the Hyatt Regency San Diego	June 6, 1996	San Diego, CA
Pain Management Study Group Meeting at the Sheraton Crescent Hotel	June 6, 1996	Phoenix, AZ

(3) Sudler & Hennessey

76. Sudler & Hennessey is a midtown Manhattan advertising and marketing firm, which caters to the pharmaceutical and healthcare industries. Sudler & Hennessey

provided and continues to provide the Defendants with strategic management services, advising them on strategies and tactics to expand the on-label and off-label use of Neurontin. Through its Intramed Educational Group division, Sudler & Hennessey also managed and coordinated various marketing events, including consultants' meetings and other peer-to-peer marketing events.

77. Sudler & Hennessey and the Defendants maintained systematic linkages between themselves, including continuing coordination between their respective marketing teams.

78. Sudler & Hennessey recommended various unlawful ways for Parke-Davis to expand off-label use. Sudler & Hennessey in fact designed the blueprint for large off-label marketing junkets. In July 1995, Sudler & Hennessey held a multi-day consultants meeting at the La Costa Resort and Spa in Carlsbad, CA. This event featured lectures about off-label uses from physicians who became regular and willing participants in the Peer Selling Sub-Enterprise, including Drs. Schachter, Browne, Morrell, Morris, Pellock and Ritaccio. Collectively, these physicians have earned more than $500,000 (not counting travel, lodging and meals benefits) by participating in the Enterprise. The Carlsbad program even included a lecture that taught attendee physicians how to participate in the peer-to-peer marketing scheme as paid speakers and/or authors. The format for the La Costa event was repeated numerous times, with new high prescribing doctors being invited to the different events.

79. Sudler & Hennessey has carried and continues to carry out many similar off-label marketing events all around the country. In those events, Sudler & Hennessey routinely uses speakers who are favorable to Neurontin.

80. Sudler & Hennessey also helped to organize the Neurobehavioral Working Group. The Group appeared to be a committee of concerned physicians from various medical fields who sought better pharmacological treatment for patients suffering from migraine, epilepsy, neuropathic pain, psychological disorders and sleep disturbances. In reality, it was a marketing tactic created by Sudler & Hennessey and funded by Parke-Davis to create publications and deliver lectures that would inform other physicians of Neurontin's off-label use in the major off-label categories, by creating the belief that these categories are interrelated. There was no scientific evidence for this claim and no clinical evidence that Neurontin was effective for any of these conditions other than adjunctive epilepsy therapy. The physician lecturers for the Neurobehavioral Working Group were physician members of the Off-Label Promotion Enterprise including Drs. Devinsky, Morrell, Schachter (who collectively received more than $200,000 for their participation in the Enterprise.)

81. Some, but not all, of the events Sudler & Hennessey presented on behalf of the Off-Label Promotion Enterprise included:

Neurontin Consultants Meeting	April 19-21, 1996	Jupiter Beach, FL
Neurontin Consultants Meeting	May 3 – 4, 1996	Philadelphia, PA
Neurontin Consultants Meeting	May 10 – 11,1996	Boston, MA
Emerging Concepts on the Use of Anticonvulsants CME at Marriott Sawgrass Resort	April 1997	Ponte Vedra, FL
Emerging Concepts on the Use of Anticonvulsants CME	May 1997	Saratoga Springs, NY
Emerging Concepts on the Use of Anticonvulsants CME	June 1997	Boston, MA
Emerging Concepts on the Use of Anticonvulsants CME	July 1997	Saratoga Springs, NY
Emerging Concepts on the Use of Anticonvulsants CME	May 1998	Hershey, PA
Consultants Conference: Neuropathic Pain Syndrome	April 20, 1996	Marco Island, FL
Current Applications in Neurological Conditions Grand Rounds at the Buckhead Resort	Sept. 27-28, 1997	Atlanta, GA

Anticonvulsants, Current Applications in Neurological Conditions ("Weekend Pain Meeting") at the Four Seasons Hotel	July 1998	Boston, MA
Anticonvulsants, Current Applications in Neurological Conditions	July 1998	New York, NY
Consultants Conference	Feb. 2-4, 1996	Marco Island, FL
Mastering Epilepsy Regional Consultants Meeting at the La Costa Resort and Spa	July 1995	Carlsbad, CA
Neurontin Consultants Meeting	April 19-21, 1996	Jupiter Beach, FL
Neurontin Consultants Meeting	May 3 – 4, 1996	Philadelphia, PA
Neurontin Consultants Meeting	May 10 – 11,1996	Boston, MA
Emerging Concepts on the Use of Anticonvulsants CME at Marriott Sawgrass Resort	April 1997	Ponte Vedra, FL
Emerging Concepts on the Use of Anticonvulsants CME	May 1997	Saratoga Springs, NY
Emerging Concepts on the Use of Anticonvulsants CME	June 1997	Boston, MA
Emerging Concepts on the Use of Anticonvulsants CME	July 1997	Saratoga Springs, NY
Emerging Concepts on the Use of Anticonvulsants CME	May 1998	Hershey, PA
Consultants Conference: Neuropathic Pain Syndrome	April 20, 1996	Marco Island, FL
Current Applications in Neurological Conditions Grand Rounds at the Buckhead Resort	Sept. 27-28, 1997	Atlanta, GA
Anticonvulsants, Current Applications in Neurological Conditions ("Weekend Pain Meeting") at the Four Seasons Hotel	July 1998	Boston, MA
Anticonvulsants, Current Applications in Neurological Conditions	July 1998	New York, NY
Consultants Conference	Feb. 2-4, 1996	Marco Island, FL
Mastering Epilepsy Regional Consultants Meeting at the La Costa Resort and Spa	July 1995	Carlsbad, CA
New Treatment Options for the Management of Pain: The Role of Anticonvulsants at the Four Seasons	April 2000	Irving, TX
Advisory Board at the Disney Yacht Club	May 26, 2000	Orlando, FL
New Directions in the Understanding and Treatment of Pain at the Plaza Hotel	March 24, 2001	New York, NY
New Directions in the Understanding and Treatment of Pain at the Hilton Novi	March 2 – 3, 2001	Detroit, MI
New Directions in the Understanding and Treatment of Pain at the Westin Galleria	May 4 – 5, 2001	Houston, TX
New Directions in the Understanding and Treatment of Pain at the Harbor Court Hotel	February 9 – 10, 2001	Baltimore, MD

New Directions in the Understanding and Treatment of Pain at the Fairmont Kansas City	March 9 – 10, 2001	Kansas City, MO
New Directions in the Understanding and Treatment of Pain at the Peabody Memphis	May 11 – 12, 2001	Memphis, TN
Advisory Board Meeting at the Grand Wailea Resort Hotel and Spa	April 14-16, 2000	Maui, HI
New Directions in the Understanding and Treatment of Pain at the Fairmont San Francisco	March 16 – 17, 2001	San Francisco, CA
Advisory Board Meeting at the Westin Resort	June 16-18, 2000	Hilton Head, SC
New Directions in the Understanding and Treatment of Pain at the Sheraton Universal City	May 18 – 19, 2001	Universal City, CA
New Directions in the Understanding and Treatment of Pain at the Miami Biltmore	May 18 – 19, 2001	Miami, FL
New Directions in the Understanding and Treatment of Pain at the Ritz Carlton New Orleans	March 23 – 24, 2001	New Orleans, LA
New Directions in the Understanding and Treatment of Pain at the Sheraton Music City	March 23 – 24, 2001	Nashville, TN
New Directions in the Understanding and Treatment of Pain at the Ritz Carlton St. Louis	March 30 – 31, 2001	St. Louis, MO

(4) MEDED/MEDCON

82. Through at least 1997, Medical Education Programs, Ltd. ("MEDED") was a pharmaceutical marketing firm located in Danbury, Connecticut. Upon information and belief, MEDED was dissolved in 1997, and its principals established a spin-off pharmaceutical marketing firm known as Medical Education Consultants, LLC ("MEDCON"), located in Danbury, Connecticut. At all times relevant hereto, MEDED, and then subsequently MEDCON, provided and continues to provide the Defendants with strategic management services, advising them on strategies and tactics to expand the on-label and off-label use of Neurontin. MEDED/MEDCON also managed and coordinated various marketing events, including regional consultant meetings for the various CBUs.

83. MEDED/MEDCON recommended various unlawful methods for the Defendants to expand off-label use and assisted in the implementation of those methods. For example, MEDED/MEDCON coordinated a series of Neuropathic Pain Consultants Meetings

held at various regional resorts during the spring of 1996 on behalf of the Southeast CBU. The speakers at these events were handpicked by Parke-Davis. These meetings were not legitimate because the number of attendees was far too large for a bona fide consultants meeting. MEDED/MEDCON also coordinated an Advisory Board on Neurontin and psychiatric uses for the Southeast CBU at the Grand Cypress Hotel in Orlando, Florida on May 2 – 4, 1997.

84. MEDED/MEDCON worked with Sudler & Hennessey and Defendants to provide services relating to the Neurobehavioral Work Group, including registering and organizing the Group's website.

85. MEDED/MEDCON also assisted the Defendants to create articles about off-label Neurontin use pursuant to the Publication Strategy, including retaining Drs. Wilder, Schachter, Longmire, and Nicholson, physician participants in the Peer Selling Sub-Enterprise who had collectively received more than $400,000 for participating in the enterprise, to lend their names to articles on Neurontin's use in pain syndromes. These articles were to be included in a supplement to the journal "Pain Digest." Upon information and belief, the physician participants did not actually write these articles. Instead, the content of these articles were developed by MEDED, and the doctors were simply paid for the use of their name. Although copies of the Neurontin pain supplement would be sent to the subscribers of Pain Digest, MEDED planned to distribute 5 times as many copies to physicians who attended off-label Neurontin events MEDED produced for Parke-Davis.

86. Some, but not all, of the events MEDED/MEDCON presented on behalf of the Off-Label Promotion Enterprise included:

Consultants Conference: Neuropathic Pain Syndrome	April 20, 1996	Marco Island, FL
Current Applications in Neurological Conditions Grand Rounds at the Buckhead Resort	Sept. 27-28, 1997	Atlanta, GA

Anticonvulsants, Current Applications in Neurological Conditions ("Weekend Pain Meeting") at the Four Seasons Hotel	July 1998	Boston, MA
Anticonvulsants, Current Applications in Neurological Conditions	July 1998	New York, NY

(5) MES

87. Medical Educations Systems ("MES") is a marketing firm which caters to the healthcare and pharmaceutical industries. MES specializes in coordinating CMEs, peer-to-peer sales events, and training pharmaceutical sales staffs. MES managed and coordinated various marketing events for the Defendants, including consultant meetings and other peer-to-peer marketing events.

88. MES and the Defendants maintained systematic linkages between themselves, including continuing coordination between their respective marketing teams.

89. MES recommended various unlawful ways for Parke-Davis to expand off-label use. For example, MES arranged what purported to be a consultants' meeting held in Chicago, Illinois on July 19 – 20, 1996. Although the topic was "Expanding the Paradigm of Antiepileptic Use," the meeting was in reality a marketing event designed to favorably tout Neurontin for off-label uses, specifically pain and psychological uses. MES has carried out many similar off-label marketing events all around the country, all "in support of Neurontin." In those events, MES routinely selects speakers known to be acceptable to Defendants and who support off-label use of Neurontin.

90. One, but not all, of the events MES presented on behalf of the Off-Label Promotion Enterprise included:

Consultants Conference	Feb. 2-4, 1996	Marco Island, FL

(6) HCC

91. Healthcare Communications Group ("HCC") was a pharmaceutical marketing firm located in New Jersey. HCC managed and coordinated various marketing events for the Defendants, including consultant meetings and other peer-to-peer marketing events. HCC has carried and continues to carry out off-label marketing events all around the country. In those events, HCC selects speakers known to be acceptable to Defendants and who support off-label use of Neurontin. Some, but not all, of the events HCC presented on behalf of the Peer Selling Sub-Enterprise included:

Emerging Concepts on the Use of Anticonvulsants CME at Marriott Sawgrass Resort	April 1997	Ponte Vedra, FL
Emerging Concepts on the Use of Anticonvulsants CME	May 1997	Saratoga Springs, NY
Emerging Concepts on the Use of Anticonvulsants CME	June 1997	Boston, MA
Emerging Concepts on the Use of Anticonvulsants CME	July 1997	Saratoga Springs, NY
Emerging Concepts on the Use of Anticonvulsants CME	May 1998	Hershey, PA

(7) CME, Inc.

92. CME, Inc., now known as CME LLC, is an accredited medical education sponsor located in Irvine, CA. CME, Inc. produces a variety of educational events, including annual congresses, conferences, and multimedia home-study products. CME, Inc. specializes in sponsorship activities that relate to mental health disorders, including publication of the journal Psychiatric Times.

93. CME, Inc. managed and coordinated various marketing events for the Defendants, including a program entitled New Frontiers in Social Phobia and Bipolar Disorder, which promoted the use of Neurontin for psychiatric uses though a series of seminars held across the country and a workbook.

8) Boron LePore & Associates

94. Boron LePore and Associates, Inc. ("Boron Lepore") is a New Jersey-based healthcare communications, marketing and pharmaceutical services company that caters to the pharmaceutical industry.

95. Boron Lapore managed and coordinated various marketing events for the Defendants, including a series of marketing teleconferences between October and December 1997 for Parke-Davis relating to the off-label use of Neurontin as epilepsy monotherapy. These teleconferences were targeted at 180 physicians in various parts of the country and related to Parke-Davis's attempt at "damage control" in the wake of the FDA's rejection of the application to market Neurontin for monotherapy.

b. The Role of Physicians

96. One of Parke-Davis's principal strategies for marketing Neurontin was to target key physicians, preferably within the major teaching hospitals, to serve as "Neurontin champions." These doctors would promote Neurontin to their peers through peer selling programs by (i) touting Neurontin's supposed off-label uses; (ii) claiming that Neurontin was being widely used by other physicians for off-label uses; (iii) suggesting mechanisms of action that could explain Neurontin's supposed efficacy in off-label areas, even though the mechanism of action in any area was not, and still is not, understood; and (iv) claiming that they were privy to the latest clinical data that had not been released yet, but which would support off-label use.

97. To lure physicians to participate in the Peer Selling Sub-Enterprise, Defendants approached target doctors and informed them of the Defendants' interest in funding research opportunities and clinical trials at their institutions. Doctors who were willing to speak favorably about Neurontin could likely receive substantial funds in the form of research grants.

Parke-Davis instructed its sales departments to select doctors at the major teaching hospitals to become "Neurontin experts" who would in turn deliver the Neurontin message to other physicians to grow Neurontin sales. This could be done formally to other physicians at marketing events or informally to colleagues within a hospital or medical practice.

98. Having recruited these physicians, the Peer Selling Sub-Enterprise created an explosion in the off-label use of Neurontin by artificially creating the perception that physicians were clinically using Neurontin and investigating its efficacy in off-label uses on their own initiative, and not as a result of the illegal marketing activities. Defendants developed a stable of physicians to create this perception. Defendants, principally through the vendor participants, paid these physicians to induce them to write journal articles and letters to the editor that favorably discussed the off-label use of Neurontin. Defendants also paid these physicians (in addition to providing free travel to resorts, free lodging and free meals) to induce them to give talks at medical education seminars, advisory boards, consultants' meetings, speakers bureaus and similar events that favorably discussed the off-label use of Neurontin. The physicians who accepted these benefits and agreed to promote Neurontin off-label to other doctors were physician participants in the Peer Selling Sub-Enterprise. The individual physician participants received tens of thousands of dollars to promote Neurontin's off-label uses. Some individual physician participants received more than $100,000.

99. Physician participants were absolutely critical to the success of the Peer Selling Sub-Enterprise and all of the marketing plans drafted by the Defendants and the vendor participants required their participation. The participation of physicians allowed the Defendants and vendor participants to disguise promotional events as educational events or consultants' meetings. Moreover, as noted above, the Defendants and vendor participants knew that peer to

peer selling was far more persuasive than traditional detailing. By funneling the payments to the physician participants through the vendor participants, the Enterprise could hide the speakers' financial ties with the Defendants, the Enterprise was able to mislead physician-listeners into believing that the speakers were not biased and that the events were not promotional. The large amounts of money the participating physicians received from the Defendants, for speaking and other purposes, was hidden from the physicians who attended events at which the participating physicians spoke.

100. Some physicians participated in the Peer Selling Sub-Enterprise by publishing favorable journal articles and letters to the editor about off-label use of Neurontin. Defendants paid large sums of money, often in the form of research grants, to the physician participants in order to publish such articles. In some cases, the physician was not required to perform any research or even write the article. Marketing firms who were financed by the Defendants ghostwrote articles under the physician participants' names. Physicians merely had to "lend" their names to the articles, in exchange for a payment.

101. Physicians who participated in the Peer Selling Sub-Enterprise, either as speakers or as authors, entered into a mutually advantageous relationship with the Defendants. The more favorable a physician's statements were, the more he or she could expect to receive in the form of speaker fees and research grants. Physicians who refused to deliver the favorable off-label message that the Defendants wanted were blackballed and would not receive additional payments.

102. The participating physicians knew that minimal scientific evidence supported the use of Neurontin for the off-label uses and that the type of clinical evidence that existed was insufficient, under the usual standards in the medical profession, to represent that

Neurontin worked for the unapproved indications. For example, on March 18, 2000, at a meeting in New York City of participating physicians who were planning new "educational" programs regarding off-label Neurontin usage, one psychiatrist admitted to his colleagues:

> (A)lmost everything I'm talking about (reports of successful off-label Neurontin usage) appears in the form of letters to the editor or open case series. The amount of controlled trials, the evidence base for this, is not very good. And there is a sense of feeling awkward—Elizabeth, this is something we should address—there's a sense of getting up there and talking about these things (off-label Neurontin usage) when, maybe, at best, there might be one or two controlled trials that support a given use.
>
> So, clinical use is running way ahead of what research is giving us. I mean, I can't remember, in psychiatry, anything like this, where there's such extensive use of drugs, without there necessarily being an indication or the data we would consider gold standard.
>
> So, one of the questions that I have for you to think about is, can we really say with any certainty that these drugs really work in the way that we're reporting? How confident are you, individually or as a group, that even without the clinical trials, that we can get up in front of clinicians and say, look, trust us that these things do work.

These doubts, as well as the limitations of the evidence that supported Neurontin's off-label use and the fact that the type of evidence assembled by Defendants would in any other circumstance be insufficient to permit a recommendation for off-label usage, were facts that had to be reported to the physicians attending events where the participating physicians spoke, in order to avoid the other information they presented from being misleading. However, despite the psychiatrist's acknowledgement that the limitations of Defendants' evidence had to be addressed, these facts were never disclosed at the events produced by the Peer Selling Sub-Enterprise or the journal articles they created.

103. Physician participants worked with, and were retained by, multiple vendor participants. All of the physician participants also had personal relationships with employees of

the Defendants, frequently Defendants recommended specific individual participants for events. Thus, a physician participant might speak at a resort for an educational event held by Sudler & Hennessey one weekend, give an almost identical presentation at a different resort hundreds of miles away for Physicians World the next weekend, and provide the same information (and misrepresentations) at a dinner meeting sometime in between for MEDED at a third location.

104. Plaintiffs do not at this time know the identity of all of the physician participants. The Off-Label Promotion Enterprise sponsored hundreds of events across the country between 1996 and 2004 and the Plaintiffs have only had an opportunity to review the records of a small subgroup of these events. Based on the records reviewed to date at least 28 individual physician participants, identified below, received $25,000 or more for participating in the Off-Label Promotion Enterprise's activities for the time period indicated below (not counting travel, food, lodging and entertainment benefits they received for events held at resorts or out of town hotels). Each of these physician participants appeared at multiple events and promoted off-label use of Neurontin at each event.

Wilder, Joe (1/94-11/97)	$307,958	Browne, Thomas (9/93-12/97)	$142,364
Ramsey, R. Eugene (2/94-12/97)	$163,446	Ferrendelli, James (11/93-10/97)	$124,863
Beydoun, Ahmad (6/94-12/97)	$122,036	Wheless, Jams (1/95-11/97)	$54,829
Pellock, John (3/94-10/97)	$119,940	Leppik, Ilo (12/93-11/97)	$49,250
Bergey, Gregory (9/93-12/97)	$106,987	Merren, Michael (3/94-11/97)	$47,606
Morrell, Martha (10/93-11/97)	$91,730	DeToledo, John (10/95-12/97)	$45,434
McLean, Michael (7/93-11/97)	$83,343	Ritaccio, Anthony (3/94-11/97)	$44,258
Sachdeo, Rajesh (3/94-12/97)	$74,954	Uthman, Basim (5/94-12/97)	$43,902
Treiman, David (4/94-10/97)	$73,118	Smith, Michael (3/94-9/97)	$40,028
Morris, George (3/94-11/97)	$72,878	Devinsky, Orrin (5/94 - 10/97)	$37,250

Schachter, Steven (5/94-9/97)	$71,477	Moshe, Solomon (4/94-12/97)	$34,250
Bruni, Joseph (10/93-12/97)	$60,585	Gelblum, Jefferey (1/96-12/97)	$28,978
Nitz, Dennis (5/95-5/96)	$58,187	Longmire, David (11/95-5/97)	$28,469
Yerby, Mark (3/94-12/97)	$57,741	Rosenfeld, William (3/94-12/97)	$26,730

2. Publication Sub-Enterprise

a. Introduction

105. In order to execute their publication strategy, Defendants also needed to generate favorable articles about Neurontin's off-label uses. However, Defendants' apparent control of this strategy had to be kept to an absolute minimum. Articles had to appear as if they emanated from independent physicians who were investigating Neurontin independently. To perform these tasks Defendants established a sub-enterprise of the Off-Label Promotion Enterprise, which would create "independent" publications. Like the Peer Selling Sub-Enterprise, the Publication Sub-Enterprise was an association in fact of medical marketing companies, participating physicians and Defendants, for the purpose of promoting off-label uses of Neurontin. Alternatively, the Publication Enterprise can be viewed as an enterprise which was separate and distinct from the Off-Label Promotion Enterprise.

106. Defendants' "publication strategy" required publications from independent physicians when in fact no such publications existed. Defendants created the Publication Sub-Enterprise to hire non-physician technical writers to create the necessary articles and then paid actual specialists to be the articles' "authors." This practice is referred to as "ghostwriting."

107. In order to monitor the status of publications, and in order to coordinate and execute the ghostwriting plan, marketing firms such as MES and AMM/Adelphi were necessary. The role played by MES and AMM/Adelphi in assisting the Defendants in creating

publications was very similar to the role played by marketing firms in the coordination of peer-to-peer marketing events.

b. MES and AMM/Adelphi

108. MES and AMM/ADELPHI, Ltd. ("AMM/Adelphi"), a marketing firm based in New York City, assisted the Defendants in publishing a variety of articles about Neurontin and off-label uses. Defendants decided what topics the papers would cover and paid all expenses in connection with the creation of these publications. Technical writers for MES and AMM/Adelphi drafted the articles. The articles were then submitted to a physician who "loaned" his or her name to the article in exchange for a payment of an honorarium. Defendants approved the topics of the articles, the content of the articles and, to the extent possible, the selection of the journal where the article was published.

109. Between 1997 and 1998, MES prepared at least 12 different articles. Although its proposal claimed to seek funding for articles relating to epilepsy, the actual articles that were developed were in fact mostly for off-label uses. These included pain (2 articles), behavioral disorders, mania and hypomania, mood and anxiety disorders, migraine, bipolar disorder, refractory epilepsy, and monotherapy. The intended articles are listed below:

Credited Author	Subject
M. Afzal Choudhry	Mental retardation (Epilepsia)
Ahmad Beydoun	Monotherapy (Neurology; Pharmacotherapy)
Mark H. Pollack	Mood and anxiety disorders (CNS Spectrums; Am J Psychiatry)
Patricia (Tricia) Suppes	Mania and hypomania (J Affective Disorders)
Basim Uthman	Monotherapy (JAMA)
Barry Gidal	Elderly patients (The Consultant Pharmacist)
Martha Morrell	Female patients (Am J Obstet Gynecol)

John M. Pellock	Mental retardation (Epilepsia)
John M. Pellock	Pediatric patients (Pediatrics)
Michael Merren	Pain and tremor (Journal of Southern Medicine)
Gail Anderson	Elderly patients (The Consultant Pharmacist)
Gail Anderson	Pharmacokinetics (Pharmacotherapy)
Maurice Druzin	Female patients (Am J Obstet Gynecol)
Hans Hansen	Chronic pain and migraine (Ann Intern Med)

110. AMM/Adelphi was retained to prepare at least 8 different case reports for the Northeast CBU alone in 1996. AMM/Adelphi noted that the physicians being used to write articles were clinicians, not scientific authors (academicians or researchers) who usually write journal articles. Most of these articles that were developed by AMM/Adelphi related to off-label uses of Neurontin, including pain, neuropathic pain, RSD, restless leg. The articles AMM/Adelphi were retained to prepare are summarized below:

Credited Author	Subject
Smith	Neurontin for Treatment of Pain
Foster	
Dwarkaneth	Neuropathic pain & RSD
Redner	
Shapiro	
Enrique Carrazana	Neuropathic pain (Journal of Pain and Symptom Management)
Steven Schachter	Neuropathic pain (Journal of Pain and Symptom Management)
Bruce Ehrenberg	
Sutherland	Psychiatric uses

111. AMM/Adelphi developed the articles using its own technical writers, with very little, or in some cases, no input from the nominal authors. This occurred even in connection with case histories that purported to describe the "author's" personal treatment of actual patients. The "authors" that approved the final drafts were paid an honorarium of $1,000.00 to lend their names to these articles.

112. After the technical writers completed their work, Parke-Davis and the marketing firms found scientific journals that would publish the articles. Defendants' role in creating, approving and sponsoring the articles was hidden from the public. For example, one of the MES articles, Gabapentin and Lamotrignine: Novel Treatments for Mood and Anxiety Disorders, supposedly written by Dr. Pollack and published in CNS Spectrums, noted that "an honorarium was received from Medical Education Systems for preparation of this article." However, it never revealed Parke-Davis's retention and payment of MES or the fact that MES personnel, while under contract to Parke-Davis, wrote the article.

113. MES and AMM/Adelphi were active participants in Defendants' scheme and were aware of, and interacted with, other participants in the fraudulent scheme. MES, AMM/Adelphi and the Defendants operated collectively, for a common purpose, and as a continuing unit to perpetrate the fraudulent scheme relating to the creation of articles promoting Neurontin.

114. MES and AMM/Adelphi's knowledge, involvement, and activity is evidenced by:

- the failure of MES to advise government regulators, private insurers, and patients, including Plaintiffs and the Class, of the existence and spread of such misinformation concerning off-label uses of Neurontin;

- the acceptance by MES of various types of incentives from Defendants in return for their agreement to write, author, and have published articles containing misrepresentations, knowing that other physicians and consumers would rely on such information; and
- the agreement of MES to permit Defendants to control the information relayed to the public in such articles.

c. Misrepresentations and Misleading Statements In Articles Created or Controlled by the Publication Enterprise

115. Publications that Defendants distributed as part of their "publication strategy," intentionally misrepresented Defendants' role in the creation and sponsorship of the publications. Physicians who reviewed these publications were led to believe that the publications were the independent, unbiased research of the authors of the articles. They were not made aware of the fact that Defendants had in fact solicited these articles or that they had paid significant sums of money in various forms to the physician authors to induce them to make favorable statements about Neurontin.

116. For example, an article widely circulated by Defendants concerning the use of Neurontin in the treatment of Restless Leg Syndrome asserted that the authors Gary A. Mellick and Larry B. Mellick had not and never would receive financial benefit from anyone with an interest in Neurontin. The Mellick brothers had in fact received tens of thousands of dollars for acting as speakers at Defendants' events. Moreover, Gary Mellick never disclosed that he was a consultant with Parke-Davis and was assisting the Company in developing the market for off-label uses of Neurontin.

117. Even in cases were physician-authors drafted the articles themselves, they did so under the same system of direction and control through which Defendants controlled speaker content. Physicians were promised grants and other gifts if they wrote favorable articles.

If a physician attempted to write a negative article, Defendants would attempt to intervene and have a more favorable draft written. If this failed, Defendants would do their best efforts to suppress the article or restrict its dissemination.

118. For example, in 1996, Parke-Davis funded a placebo-controlled clinical trial conducted by Dr. Kenneth Gorson, a doctor at St. Elizabeth's Hospital in Boston, Massachusetts. On August 23, 1997, Gorson submitted a draft of his study to Parke-Davis, accompanied by an abstract. The results of Gorson's study were negative. Gorson's abstract plainly stated that the study did not support Neurontin's use for diabetic peripheral neuropathy. Its conclusion stated that gabapentin "is probably no more effective than placebo in the treatment of painful diabetic neuropathy."

119. Defendants attempted to revise the draft abstract to give it a more favorable conclusion. In January 1998, Parke-Davis circulated a different abstract of the Gorson article which contained a the revised conclusion. The conclusion of the abstract circulated by Parke-Davis stated: "Gabapentin may be effective in the treatment of painful diabetic neuropathy. Our results suggest that further studies evaluating higher dosages of gabapentin are warranted."

120. Dr. Gorson refused to adopt this revision. In February 1999, more than one year later and almost two years after the study's completion, the results of Dr. Gorson's study were published in a letter to the editor of the Journal of Neurology, Neurosurgury & Psychiatry, vol. 66, pages 251-52. The article concluded, "The results of this study suggest that gabapentin is probably ineffective or only minimally effective for the treatment of painful diabetic neuropathy at a dosage of 900 mg/day".

121. Despite Gorson's refusal to sugarcoat his manuscript, Parke-Davis still attempted to control the content of the article. Parke-Davis submitted to the Drugdex Drug Information System, a widely used computer database that contains drug information and article citations, a draft of the article which contained language consistent with the false abstract circulated by Parke-Davis but which was not contained in the actual article. Based on this information, Drugdex published a citation for the Gorson article, which falsely stated: "the authors suggest that higher doses of gabapentin are needed." No such language is in the article. The Drugdex article omits the author's conclusion that gabapentin is "probably ineffective" for the treatment of painful diabetic neuropathy.

122. The final method by which Defendants controlled the stream of published information was through its policy of publishing only favorable results of its own internal trials and suppressing results that were unfavorable. In the case of an early trial that failed to show Neurontin's efficacy for migraine, the results were never published. In the case of a clinical trial that failed to show Neurontin's efficacy for bipolar disorder, the publication of results was delayed until the patent life was set to expire, and even then, Defendants never forwarded a copy of the article to DRUGDEX.

123. Although Plaintiffs are aware of the policy of suppressing unfavorable studies because of the express terms of the corporate decisions implementing the Publication Strategy, all information regarding negative studies funded by Parke-Davis remains in the sole possession of Parke-Davis and/or members of the Off-Label Promotion Enterprise. Without access to records of the studies that were funded and the results of those studies, Plaintiffs cannot identify specific negative findings. Defendants have never produced the results of these studies to the public or to the Plaintiffs and their attorneys.

E. Defendants' Use of the Entire Off-Label Promotion Enterprise to Make False Statements to Physicians

1. Introduction

124. When presenting off-label information about Neurontin to physicians in response to unsolicited requests for information on unapproved uses, Defendants were required to provide fair and balanced information. Defendants were also required to provide fair and balanced information whenever it engaged in promotional activities. Fair balance was not limited to written materials but all presentations. Defendants knew that whenever they were required to provide fair and balanced information, federal law and industry standards required them to provide any negative information as well as positive information about their drug products.

125. Within the medical community, in the context of describing properties of approved prescriptions drugs, the terms "effective" and "efficacy" have specific and well-understood meanings. Because the FDA will only find a drug product to be effective if the proposed use is supported by well designed, placebo-controlled clinical trials that establish a causal relationship to a statistically significant degree, a statement that a drug is "effective," or "works," or "has been proven to . . ." is understood to mean that well controlled clinical studies support the use. To make such a statement without such clinical trial proof is misleading. Further, failure to inform physicians that no placebo-controlled clinical trials support a representation of drug efficacy is a violation of a pharmaceutical companie's obligation to disclose.

126. Although Defendants have extensively promoted Neurontin for off-label purposes, few placebo-controlled, clinical studies have been conducted on off-label uses of Neurontin. Most of those that have been conducted were negative or inconclusive. Placebo-controlled clinical trials for Neurontin's use for bipolar disorder, unipolar disorder, essential

tremor, spasticity, controlled diabetic pain, and panic disorder have all failed to show that Neurontin is effective for those conditions. Any presentation concerning Neurontin's use for indications other than those approved by the FDA that purports to rely on clinical or published evidence must also describe those clinical studies that have found that Neurontin is not effective for off-label uses. Where such information is not provided, any statements about Neurontin's effectiveness for off-label use is false, misleading, distorted, inaccurate, unfair, imbalanced and omits material facts necessary to be disclosed.

127. Further, federal law and industry standards also prohibited Defendants from misrepresenting scientific evidence that supported (or failed to support) claims that a drug was effective for a specific condition. Thus, anecdotal evidence of a drug's usefulness for a given condition could not be presented as the equivalent of the findings of a well-designed clinical trial. To fail to comply with these standards violated the Defendants' legal duty to provide accurate and non-misleading information.

128. The Off-Label Promotion Enterprise routinely and knowingly provided false, inaccurate, misleading, distorted, unfair and unbalanced information about Neurontin's use for unapproved indications. Without discovery, Plaintiffs cannot catalog each misrepresentation and/or misleading statement about Neurontin because Plaintiffs do not possess all transcripts of all meetings. The vast majority of these transcripts are in the possession of the Defendants and/or other members of the Off-Label Promotion Enterprise and have not been produced for the Plaintiffs. Plaintiffs' attorneys do, however, possess representative transcripts which demonstrate that the participating physicians made the same or substantially similar representations when they gave presentations regarding off-label Neurontin at different events arranged by the Off-Label Promotion Enterprise, and that once the participating vendors

assembled the content of an off-label promotional (or educational) program, they repeated the program numerous times on numerous occasions across the country. As a result, the Plaintiffs are aware of misrepresentations, misleading statements and material omissions that were made in specific events as well as misrepresentations, misleading statements and material omissions that were likely made in numerous other events. A description of the false statements, misleading statements and material omissions follow.

2. False and Misleading Statements About Pain

129. At each of the presentations known to the Plaintiffs concerning Neurontin on pain, at least one of the presenters expressly stated or implied that Neurontin was effective for the treatment of pain. A representative statement was made by Dr. David Longmire, a participating physician, at the Jupiter Beach Consultants' meeting in April 1996 when he stated that Neurontin was effective for the treatment of pain. Dr. Longmire repeated that statement at a May 1996 Consultants' Meeting at the Ritz Carlton in Boston. Another physician participant, Dr. Steven Schacter made a similar statement at the May 1996 meeting when he stated that "pain specialists are finding that low dosages of Neurontin are effective." Plaintiffs are aware of comparable statements made by another physician participant, Dr. Bruce Nicholson, in April 1996 at the Jupiter Beach Consultants' Meeting, in May 1996 at the Boston Ritz Carlton Consultants Meeting and in June 1996 at a Philadephia Consultants' Meeting. Upon information and belief, similar statements were made at all events presented by the Off-Label Promotion Enterprise that discussed Neurontin's use for pain indications. These events include, but are not limited to the following:

Neurontin Consultants Meeting	April 19-21, 1996	Jupiter Beach, FL
Neurontin Consultants Meeting	May 3 – 4, 1996	Philadelphia, PA
Neurontin Consultants Meeting	May 10 – 11,1996	Boston, MA
Advisory Board Meeting at the Grand Wailea Resort Hotel and Spa	April 14-16, 2000	Maui, HI

Merritt-Putnam Speakers Training Advanced Perspectives in the Management of Neurological and Mood Disorders at the Enchantment Resort	April 28-30, 2000	Sedona, AZ
New Treatment Options for the Management of Pain: The Role of Anticonvulsants at the Four Seasons	April 2000	Irving, TX
Advisory Board at the Disney Yacht Club	May 26, 2000	Orlando, FL
New Directions in the Understanding and Treatment of Pain at the Plaza Hotel	March 24, 2001	New York, NY
New Directions in the Understanding and Treatment of Pain at the Hilton Novi	March 2 – 3, 2001	Detroit, MI
New Directions in the Understanding and Treatment of Pain at the Westin Galleria	May 4 – 5, 2001	Houston, TX
New Directions in the Understanding and Treatment of Pain at the Harbor Court Hotel	February 9 – 10, 2001	Baltimore, MD
New Directions in the Understanding and Treatment of Pain at the Fairmont Kansas City	March 9 – 10, 2001	Kansas City, MO
New Directions in the Understanding and Treatment of Pain at the Peabody Memphis	May 11 – 12, 2001	Memphis, TN
Advisory Board Meeting at the Grand Wailea Resort Hotel and Spa	April 14-16, 2000	Maui, HI
New Directions in the Understanding and Treatment of Pain at the Fairmont San Francisco	March 16 – 17, 2001	San Francisco, CA
Advisory Board Meeting at the Westin Resort	June 16-18, 2000	Hilton Head, SC
New Directions in the Understanding and Treatment of Pain at the Sheraton Universal City	May 18 – 19, 2001	Universal City, CA
New Directions in the Understanding and Treatment of Pain at the Miami Biltmore	May 18 – 19, 2001	Miami, FL
New Directions in the Understanding and Treatment of Pain at the Ritz Carlton New Orleans	March 23 – 24, 2001	New Orleans, LA
New Directions in the Understanding and Treatment of Pain at the Sheraton Music City	March 23 – 24, 2001	Nashville, TN
New Directions in the Understanding and Treatment of Pain at the Ritz Carlton St. Louis	March 30 – 31, 2001	St. Louis, MO
New Advances in the Treatment of Neuropathic Pain	October 9 – 11, 1998	Madeira, Portugal

130. The speakers who made these statements did not have any clinical evidence to support such claims. These statements implied that clinical trial evidence sufficient to establish causation existed. However, with the exception of Neurontin's use for post herpetic neuralgia, no clinical trial evidence exists that supports any claim that Neurontin is effective for the treatment of pain.

131. In almost none of the presentations in which Neurontin's use for pain was promoted did the physician participant or any person connected to the Off-Label Promotion Enterprise acknowledge that there was no clinical trial evidence to support a claim of efficacy. Defendants' failure to disclose this material information made any statement stating that Neurontin was effective for any pain syndrome other than post herpetic neuralgia false and misleading.

132. At every presentation concerning Neurontin's use for pain, neither the participating physicians, nor the participating vendors, nor the Defendants informed the attendee physicians that Defendants had deliberately suppressed negative studies pursuant to the Publication Strategy. Upon information and belief, negative studies did in fact exist that indicated or found that Neurontin was not effective for pain and information regarding these studies was not disclosed.

133. At every presentation concerning Neurontin's use for pain, anecdotal evidence was presented to support Neurontin's use. At none of the presentations, however, was anecdotal evidence presented of Neurontin's failure to treat pain, even though such evidence had been made known to Defendants. Defendants' intentional failure to provide a fair and balanced presentation of the anecdotal information concerning Neurontin's treatment for pain made their presentation false and misleading.

134. Although they were not supposed to discuss off-label indications with physicians, Parke-Davis sales representatives regularly made false statements to doctors about Neurontin's utility in treating pain. The following are representative false statements by the sales force. Plaintiffs were only able to obtain evidence of such statements for a limited time period between 1995 and 1997, but are aware of "verbatim" reports that exist for the last several years.

Upon information and belief, review of recent verbatim reports will demonstrate that similar statements were regularly made by the Defendants' sales forces from 1999 through 2004.

- In October 1995, a Parke-Davis sales representative stated that Neurontin had received a "[n]ew indication for chronic pain."
- In December 1995 a Parke-Davis sales representative stated that Neurontin was a "[g]ood anticonvulsant for chronic pain and restless leg syndrome."
- In July 1996, a Parke-Davis sales representative stated that Neurontin was "[e]ffective for many types of chronic pain."
- In December 1996, a Parke-Davis sales representative stated that Neurontin was "[g]ood for back pain; neuropathic pains."

3. Statements Regarding Diabetic Peripheral Neuropathy

135. Prior to October 16, 1997, Parke-Davis had no reasonable basis to claim or suggest that Neurontin was effective or could be possibly effective to treat Diabetic Peripheral Neuropathy. Nonetheless at events produced by the Off-Label Marketing Enterprise, physician participants routinely stated that Neurontin was effective for this condition. A representative statement was made at the Jupiter Beach Consultants Meeting in April 1996, when Dr. Nicholson stated that diabetic neuropathy patients "will" have their burning sensations relieved. Upon information and belief, similar statements were made at all events presented by the Off-Label Promotion Enterprise that discussed Neurontin's use as a treatment for diabetic peripheral neuropathy. These events include, but are not limited to, the following events:

Neurontin Consultants Meeting	April 19-21, 1996	Jupiter Beach, FL
New Advances in the Treatment of Neuropathic Pain	October 9 – 11, 1998	Madeira, Portugal

136. There was no clinical trial support for this assertion, when this statement and other comparable statements were made.

137. In 1996, Parke-Davis funded a placebo controlled clinical trial conducted by Dr. Kenneth Gorson, a doctor at St. Elizabeth's Hospital in Boston, MA, on the use of Neurontin as a treatment for diabetic peripheral neuropathy. On August 23, 1997, Dr. Gorson submitted a draft of his study to Parke-Davis, accompanied by an abstract. The results of Dr. Gorson's study were negative. Nonetheless, as described above, Parke-Davis wrote and circulated an abstract that hid and misrepresented Dr. Gorson's negative findings.

138. Defendants caused the Drugdex Information System to include language that falsely and inaccurately describes Dr. Gorson's findings in its citation to Dr. Gorson's article. The Drugdex citation to Dr. Gorson's article falsely states that "the authors suggest that higher doses of gabapentin are needed." This language is consistent with the false abstract Parke-Davis circulated but no such language appears in the article the Drugdex citation purports to summarize. The Drugdex article also omits the author's conclusion that gabapentin is "probably ineffective" for the treatment of painful diabetic neuropathy. Drugdex included its version of the citation after Parke-Davis approved the proposed article and corrected and updated citations Drugdex sent it prior to publication. Therefore, Defendants are responsible for the circulation of false and misleading information regarding the Gorson study and Neurontin's effectiveness for diabetic peripheral neuropathy.

139. After it received the results of the Gorson study, the Off-Label Promotion Enterprise continued to present numerous events at which Neurontin's use for diabetic peripheral neuropathy was discussed. The physician participants at these presentations failed to describe the results and conclusions of Dr. Gorson's study, and Defendants' representatives at these

events also did not provide such information. Defendants' failure to describe negative studies as well as positive studies breached their obligation to provide fair and balanced information and made their representations regarding Neurontin's use for diabetic peripheral neuropathy false and misleading.

4. Representations Regarding Restless Leg Syndrome And RSD

140. At events produced by the Off-Label Promotion Enterprise, physician participants routinely stated that Neurontin was effective for the treatment of Restless Leg syndrome or RSD. Events presented by the Off-Label Promotion Enterprise that discussed Neurontin's use as a treatment for restless leg syndrome or RSD, included, but are not limited to, the following event:

Advisory Board Meeting at the Hyatt Regency Hotel March 29, 2000 San Antonio, TX

141. The speakers who made these statements did not have any clinical evidence to support such claims. These statements implied that clinical trial evidence sufficient to establish causation existed. However, as discussed below, the clinical studies in existence do not find that Neurontin is effective for the treatment of restless leg syndrome or RSD.

142. Upon information and belief, in the presentations in which Neurontin's use for restless leg syndrome or RSD was promoted neither the physician participants nor any person connected to the Off-Label Promotion Enterprise acknowledged the lack of any clinical trial evidence to support a claim of efficacy. Defendants' failure to disclose this material information made any statement stating that Neurontin was effective for these indications false and misleading.

143. Upon information and belief, at every presentation concerning Neurontin's use for restless leg syndrome or RSD, neither the participating physicians, nor the participating vendors, nor the Defendants informed the attendee physicians that Defendants had deliberately

suppressed negative studies pursuant to the Publication Strategy. As described below, at least one negative study existed which found that Neurontin was not effective for these conditions, and upon information and belief, the results of this study were never disclosed when Neurontin's use for restless leg syndrome or RSD was discussed.

144. In 1996, Parke-Davis funded an open label study conducted by Dr. Bruce Ehrenberg of the New England Medical Center on whether Neurontin was effective for periodic limb movement, a sleep disorder closely related to restless leg syndrome. Dr. Ehrenberg's study was negative. Less than half the participants who took the drug had improved sleep, and Neurontin had no effect on more than half. Moreover, the drug did not affect any of the participants' limb movements during sleep.

145. Parke-Davis's medical liaisons falsely told physicians that Dr. Ehrenberg's patients had a 90% response rate to Neurontin. In a June 1996 conference call taped by Dr. David Franklin, medical liaisons discussed making such assertions routinely. Neither medical liaisons nor physician participants amended their statements to physicians once the results of Dr. Ehrenberg's study were known.

146. Former Parke-Davis officials have admitted that although the results were not favorable, the results of Ehrenberg's study should have been published and made known to clinicians. Indeed, Parke-Davis hired AMM/Adelphi to organize his data and to develop a manuscript for him. After the results were received, however, Parke-Davis took no steps to publish an article based on Dr. Ehrenberg's results. Parke-Davis's actions were consistent with the publication strategy, which only intended to publish studies with favorable results. Parke-Davis's policy of only publishing and disclosing the results of favorable studies directly violates

it obligation to disclose favorable and unfavorable results pursuant to its obligation to only make fair and balanced statements relating to its drug products.

147. Upon information and belief, at every presentation concerning Neurontin's use for restless leg syndrome and RSD, anecdotal evidence was presented to support Neurontin's use. At none of the presentations, however, was anecdotal evidence presented of Neurontin's failure to treat restless leg syndrome and RSD, even though such evidence was known by Defendants. Defendants' intentional failure to provide a fair and balanced presentation of the anecdotal information concerning Neurontin's treatment for restless leg syndrome and RSD made their presentations false and misleading.

148. Although they were not supposed to discuss off-label indications with physicians, Parke-Davis sales representatives regularly made false statements to doctors about Neurontin's utility in treating restless leg syndrome. The following are representative false statements by the sales force. Plaintiffs were only able to obtain evidence of such statement for a limited time period between 1995 and 1997, but are aware of "verbatim" reports that exist for the last several years. Upon Information and belief, review of recent verbatim reports will demonstrate that similar statement were regularly made by the Defendants' sales forces from 1999 through 2004.

- In August 1996, a Parke-Davis sales representative falsely stated that Neurontin was "Effective in controlling postherpetic pain; restless leg syndrome, peripheral neuropathy, migraine headache."
- In December 1996, a Parke-Davis sales representative stated that Neurontin was "Good for restless leg syndrome."

5. Representations Regarding Bipolar Disorder

149. In May 1995, when Parke-Davis created its original marketing assessment for the use of Neurontin to treat bipolar disorder, which is commonly called manic depression, it knew that there was no scientific rationale for Neurontin being an effective agent for treatment. Nonetheless, it planned to promote, and intended the Off-Label Promotion Enterprise to promote, Neurontin heavily for bipolar disorder.

150. At events produced by the Off-Label Promotion Enterprise, physician participants routinely stated that Neurontin was effective for the treatment of bipolar disorder. Events presented by the Off-Label Promotion Enterprise that discussed Neurontin's use as a treatment for bipolar disorder included, but are not limited to, the following events:

Advisory Board Meeting at the Hyatt Regency Hotel	March 29, 2000	San Antonio, TX
Parke-Davis Speakers Bureau Meeting at the Fairmont Scottsdale Princess	January 21-23, 2000	Scottsdale, AZ
Merritt-Putnam Speakers Bureau Current Perspectives in the Understanding of Neurobehavioral Disorders at the Four Seasons Regent Beverly Wilshire	March 24-26, 2000	Beverly Hills, CA
Merritt-Putnam Speakers Bureau at the Wyndham New Orleans at Canal Place	April 7-9, 2000	New Orleans, LA
Merritt-Putnam Speakers Training Advanced Perspectives in the Management of Neurological and Mood Disorders at the Enchantment Resort	April 28-30, 2000	Sedona, AZ
1998 CME Psychiatry Dinner Meeting and Teleconference Series: Dinner Meeting at Maison Robert	March 16, 1998	Boston, MA
1998 CME Psychiatry Dinner Meeting and Teleconference Series: Dinner Meeting at Sunset Grill	March 16, 1998	Nashville, TN
1998 CME Psychiatry Dinner Meeting and Teleconference Series: Dinner Meeting at the Pescatore Fish Cafe	March 16, 1998	Seattle, WA
1998 CME Psychiatry Dinner Meeting and Teleconference Series: Dinner Meeting at Patrick's Bayside Bistro	March 17, 1998	St. Pete's Beach, FL

1998 CME Psychiatry Dinner Meeting and Teleconference Series: Dinner Meeting at the Heathman Hotel	March 17, 1998	Portland, OR
1998 CME Psychiatry Dinner Meeting and Teleconference Series: Dinner Meeting at the Downtown Club	March 18, 1998	Philadelphia, PA
1998 CME Psychiatry Dinner Meeting and Teleconference Series: Dinner Meeting at Morton's of Chicago – Buckhead	March 18, 1998	Atlanta, GA
1998 CME Psychiatry Dinner Meeting and Teleconference Series: Dinner Meeting at the Huntington Hotel	March 18, 1998	San Francisco, CA
1998 CME Psychiatry Dinner Meeting and Teleconference Series: Dinner Meeting at the Brass Elephant	March 19, 1998	Baltimore, MD
1998 CME Psychiatry Dinner Meeting and Teleconference Series: Dinner Meeting at Ristorante DeGrezia	March 19, 1998	New York, NY
The Use of Anticonvulsants in Psychiatry	October 23 – 25, 1998	Barcelona, Spain

151. The speakers who made these statements did not have any clinical evidence to support such claims. These statements implied that clinical trial evidence sufficient to establish causation existed, but as discussed below, clinical studies that were conducted did not find that Neurontin is effective for the treatment of bipolar disorder. On every occasion the Off-Label Promotion Enterprise gave a presentation on the use of Neurontin for bipolar disorder without informing physicians that there was no scientific basis for using Neurontin, it omitted to inform the physician attendees of material information that was required to be presented in order for its statements on the use of Neurontin to not be misleading and false and to satisfy its obligation to provide fair and balanced information.

152. As early as May 20, 1997, Parke-Davis knew that clinical trial evidence established that Neurontin was not significantly superior to placebo in treating bipolar disorder. At the 1997 Annual Meeting of the American Psychiatric Association in San Diego, CA , investigators presented the results of a placebo controlled clinical trial comparing placebo,

lamotrigine and Neurontin on depression and bipolar patients that established that Neurontin was not significantly more effective than placebo and considerably less effective than a competitor drug, lamotrigine. By the third quarter of 1997, Parke-Davis knew that the results of its own clinical trial of Neurontin showed that placebo was more effective than Neurontin in treating bipolar disorder.

153. Although Parke-Davis knew the results of its negative bipolar disorder clinical trial as early as 1997, it did not publish the results until 2000. Nor did it halt the sponsorship of events that promoted Neurontin as an effective treatment of bipolar disorder and other psychiatric conditions. Further, although Parke-Davis contends it informs Drugdex of all articles concerning Neurontin that are not contained in Drugdex's monograph on Neurontin, Drugdex has never included citations to either of the articles that document the negative clinical trials for bipolar disorder.

154. Regardless of the clinical trial results, the Off-Label Promotion Enterprise continued to make presentations to physician attendees where Neurontin was promoted for use with bipolar disorder patients. In most of these presentations, the attendee physicians were not informed of the negative clinical trial evidence. For example, the Off-Label Promotion Enterprise created and sponsored a series of dinner meetings for psychiatrists entitled "Closing the Psychiatry-Neurology Divide: Emerging Uses of Anticonvulsants." This program was presented dozens of times in 1998, including one in St. Petersburg, Florida at Patrick's Bayside Inn. As part of the program, psychiatrists were informed Neurontin was indicated for bipolar disorder, that early evidence suggested that it had anti-depressive and mood stabilizing effects, and that "data are increasing but currently limited to favorable case reports and open trials." The

program did not inform attendees of the unfavorable clinical trials that found that Neurontin was not effective for bipolar disorder and that it was less effective than a placebo.

155. Upon information and belief, anecdotal evidence was presented to support Neurontin's use at every presentation concerning Neurontin's use for bipolar disorder. At none of the presentations, however, was anecdotal evidence presented of Neurontin's failure to treat bipolar disorder patients, even though such evidence had been made known to Defendants. Defendants' intentional failure to provide a fair and balanced presentation of the anecdotal information concerning Neurontin's treatment for bipolar disorder made their presentations false and misleading.

156. Although they were not supposed to discuss off-label indications with physicians, after placebo-controlled clinical results established that Neurontin was not effective for the treatment of bipolar disorder, Parke Davis's sales force nonetheless regularly made false statements about Neurontin's utility in treating bipolar disorder. Plaintiffs were only able to obtain evidence of such statement for a limited time period between 1995 and 1997, but are aware of "verbatim" reports that exist for the last several years. Upon information and belief, review of recent verbatim reports will demonstrate that similar statement were regularly made by the Defendants' sales forces from 1999 through 2004. Representative statements made to physicians include:

- At a Parke-Davis marketing event in 1997, Parke-Davis falsely stated that Neurontin was "effective" for "bipolar."
- In December 1998, a Parke-Davis sales representative falsely stated to a physician that Neurontin was an "effective treatment of bipolar disorder."

- At a Parke-Davis marketing event in December 1998, Parke-Davis falsely stated that Neurontin was "Effective on bipolar."
- At a Parke-Davis marketing event at the airport Marriott in San Francisco in August 1998, Parke-Davis falsely stated that Neurontin was "Innovative and effective …for bipolar II."

6. Representations Regarding Social Phobia

157. At events produced by the Off-Label Promotion Enterprise, physician participants routinely stated that Neurontin was effective for the treatment of social phobia. Events presented by the Off-Label Promotion Enterprise that discussed Neurontin's use as a treatment for social phobia included, but are not limited to, the following events:

Advisory Board Meeting at the Hyatt Regency Hotel	March 29, 2000	San Antonio, TX
Parke-Davis Speakers Bureau Meeting at the Fairmont Scottsdale Princess	January 21-23, 2000	Scottsdale, AZ
Merritt-Putnam Speakers Bureau Current Perspectives in the Understanding of Neurobehavioral Disorders at the Four Seasons Regent Beverly Wilshire	March 24-26, 2000	Beverly Hills, CA
Merritt-Putnam Speakers Bureau at the Wyndham New Orleans at Canal Place	April 7-9, 2000	New Orleans, LA
Merritt-Putnam Speakers Training Advanced Perspectives in the Management of Neurological and Mood Disorders at the Enchantment Resort	April 28-30, 2000	Sedona, AZ
1998 CME Psychiatry Dinner Meeting and Teleconference Series: Dinner Meeting at Maison Robert	March 16, 1998	Boston, MA
1998 CME Psychiatry Dinner Meeting and Teleconference Series: Dinner Meeting at Sunset Grill	March 16, 1998	Nashville, TN
1998 CME Psychiatry Dinner Meeting and Teleconference Series: Dinner Meeting at the Pescatore Fish Cafe	March 16, 1998	Seattle, WA
1998 CME Psychiatry Dinner Meeting and Teleconference Series: Dinner Meeting at Patrick's Bayside Bistro	March 17, 1998	St. Pete's Beach, FL

1998 CME Psychiatry Dinner Meeting and Teleconference Series: Dinner Meeting at the Heathman Hotel	March 17, 1998	Portland, OR
1998 CME Psychiatry Dinner Meeting and Teleconference Series: Dinner Meeting at the Downtown Club	March 18, 1998	Philadelphia, PA
1998 CME Psychiatry Dinner Meeting and Teleconference Series: Dinner Meeting at Morton's of Chicago – Buckhead	March 18, 1998	Atlanta, GA
1998 CME Psychiatry Dinner Meeting and Teleconference Series: Dinner Meeting at the Huntington Hotel	March 18, 1998	San Francisco, CA
1998 CME Psychiatry Dinner Meeting and Teleconference Series: Dinner Meeting at the Brass Elephant	March 19, 1998	Baltimore, MD
1998 CME Psychiatry Dinner Meeting and Teleconference Series: Dinner Meeting at Ristorante DeGrezia	March 19, 1998	New York, NY
The Use of Anticonvulsants in Psychiatry	October 23 – 25, 1998	Barcelona, Spain

Upon information and belief, at each of these events, participating physicians expressly stated or implied that Neurontin was effective for the treatment of social phobia.

158. The speakers who made these statements did not have any clinical evidence to support such claims. These statements implied that clinical trial evidence sufficient to establish causation existed, but as discussed below, the only clinical study conducted was inconclusive regarding Neurontin's effectiveness for the treatment of social phobia. Prior to its receipt of results of its social phobia clinical trial, Parke-Davis had no reasonable scientific basis for claiming that Neurontin was effective in treating social phobia, because no clinical trial data existed.

159. Even after July 22, 1997, when Parke-Davis received results from its clinical study, it could not state that clinical trial evidence demonstrated Neurontin's efficacy for social phobia. While results were generally favorable on the small sample that completed the study, there were wide inexplicable discrepancies in efficacy between male subjects and female

subjects, and between individuals above age 35 compared to those below age 35. The authors admitted that the data was limited, did not conclude that Neurontin was effective, and acknowledged that further studies were necessary to determine whether a dose-response relationship existed. Any statement made by Parke-Davis that claimed or suggested that Neurontin was effective to treat social phobia that did not disclose the limitations of the clinical trial evidence was not fair and balanced and consequently was false and misleading. Upon information and belief, no such information was provided in the events that discussed treatment of Neurontin for social phobia.

160. At every presentation concerning Neurontin's use for social phobia, neither the participating physicians, nor the participating vendors, nor the Defendants informed the attendee physicians that Defendants had deliberately suppressed negative studies pursuant to the Publication Strategy. Upon information and belief, there were in fact negative studies that indicated or found that Neurontin was not effective for social phobia and information regarding these studies was not disclosed.

161. At every presentation concerning Neurontin's use for social phobia, anecdotal evidence was presented to support Neurontin's use. At none of the presentations, however, was anecdotal evidence presented of Neurontin's failure to treat pain even though such evidence had been made known to Defendants. Defendants' intentional failure to provide a fair and balanced presentation of the anecdotal information concerning Neurontin's treatment for pain made their presentation false and misleading.

7. Representations Regarding Panic Disorder

162. Without favorable results from a well-designed panic disorder clinical trial that established Neurontin's efficacy for that condition, Parke-Davis had no reasonable scientific basis for claiming that Neurontin was effective in treating panic disorder. Nonetheless at events

produced by the Off-Label Promotion Enterprise, physician participants routinely stated that Neurontin was effective for the treatment of panic disorder. Events presented by the Off-Label Promotion Enterprise that discussed Neurontin's use as a treatment for panic disorder included, but are not limited to, the following events:

Advisory Board Meeting at the Hyatt Regency Hotel	March 29, 2000	San Antonio, TX
Parke-Davis Speakers Bureau Meeting at the Fairmont Scottsdale Princess	January 21-23, 2000	Scottsdale, AZ
Merritt-Putnam Speakers Bureau Current Perspectives in the Understanding of Neurobehavioral Disorders at the Four Seasons Regent Beverly Wilshire	March 24-26, 2000	Beverly Hills, CA
Merritt-Putnam Speakers Bureau at the Wyndham New Orleans at Canal Place	April 7-9, 2000	New Orleans, LA
Merritt-Putnam Speakers Training Advanced Perspectives in the Management of Neurological and Mood Disorders at the Enchantment Resort	April 28-30, 2000	Sedona, AZ
1998 CME Psychiatry Dinner Meeting and Teleconference Series: Dinner Meeting at Maison Robert	March 16, 1998	Boston, MA
1998 CME Psychiatry Dinner Meeting and Teleconference Series: Dinner Meeting at Sunset Grill	March 16, 1998	Nashville, TN
1998 CME Psychiatry Dinner Meeting and Teleconference Series: Dinner Meeting at the Pescatore Fish Cafe	March 16, 1998	Seattle, WA
1998 CME Psychiatry Dinner Meeting and Teleconference Series: Dinner Meeting at Patrick's Bayside Bistro	March 17, 1998	St. Pete's Beach, FL
1998 CME Psychiatry Dinner Meeting and Teleconference Series: Dinner Meeting at the Heathman Hotel	March 17, 1998	Portland, OR
1998 CME Psychiatry Dinner Meeting and Teleconference Series: Dinner Meeting at the Downtown Club	March 18, 1998	Philadelphia, PA
1998 CME Psychiatry Dinner Meeting and Teleconference Series: Dinner Meeting at Morton's of Chicago – Buckhead	March 18, 1998	Atlanta, GA
1998 CME Psychiatry Dinner Meeting and Teleconference Series: Dinner Meeting at the Huntington Hotel	March 18, 1998	San Francisco, CA

1998 CME Psychiatry Dinner Meeting and Teleconference Series: Dinner Meeting at the Brass Elephant	March 19, 1998	Baltimore, MD
1998 CME Psychiatry Dinner Meeting and Teleconference Series: Dinner Meeting at Ristorante DeGrezia	March 19, 1998	New York, NY
The Use of Anticonvulsants in Psychiatry	October 23 – 25, 1998	Barcelona, Spain

163. The speakers who made these statements did not have any clinical evidence to support such claims. These statements implied that clinical trial evidence sufficient to establish causation existed, but as discussed below, clinical studies that were conducted did not find that Neurontin is effective for the treatment of panic disorder. On every occasion the Off-Label Promotion Enterprise gave a presentation on the use of Neurontin for panic disorder without informing physicians that there was no scientific basis for using Neurontin, it omitted to inform the physician attendees of material information that was required to be presented in order for its statements on the use of Neurontin to not be misleading and false and to satisfy its obligation to provide fair and balanced information.

164. In October 1997, Parke-Davis received results of its own clinical trial that found that Neurontin was no more efficacious than placebo in treating panic disorder. Parke-Davis did not publish the results of the negative panic disorder clinical trial until 2000. Regardless of the results of the clinical trial, the Off-Label Promotion Enterprise continued to make presentations to physician attendees where Neurontin was promoted for use with panic disorder patients. In most of these presentations, the attendee physicians were not informed of the negative clinical trial evidence.

165. Upon information and belief, at every presentation concerning Neurontin's use for bipolar disorder, anecdotal evidence was presented to support Neurontin's use. At none of the presentations, however, was anecdotal evidence presented of Neurontin's failure to treat

panic disorder patients, even though such evidence had been made known to Defendants. Defendants' intentional failure to provide a fair and balanced presentation of the anecdotal information concerning Neurontin's treatment for bipolar disorder made their presentations false and misleading.

8. Representations Regarding Monotherapy

166. In numerous presentations produced by the Off-Label Promotion Enterprise, physician participants asserted that Neurontin was effective monotherapy for the treatment of epilepsy, despite the fact that it had only been approved by the FDA for adjunct therapy. As early as November 1995, Parke-Davis knew that clinical trial evidence demonstrated that Neurontin was not an effective monotherapy treatment. Notwithstanding its knowledge of the unsuccessful clinical trials, the Off-Label Promotion Enterprise, under Parke-Davis's control, continued to make false representations about Neurontin's efficacy as a monotherapy medication and failed to disclose to most attendee physicians the negative clinical trial evidence in its possession.

167. For example, at the Jupiter Beach consultants' meeting in August 1996, Dr. Harden and Dr. LeRoy gave presentations that claimed that Neurontin was effective for monotherapy. Drs. Harden and Leroy misrepresented the results of Clinical Study 945-82, both by claiming that the study did not evidence a failure of Neurontin efficacy and by misrepresenting the lack of a dose response. Furthermore, Dr. Leroy misrepresented that a Eastern European clinical trial had been successful when in fact the double blind codes of the study had not been broken and patient recruitment had not been completed. Notwithstanding that the only long-term clinical trial of Neurontin as monotherapy at the time of the Jupiter Beach meeting demonstrated that Neurontin was not effective for that use, attendees at Jupiter Beach

came away with the message that Neurontin was effective. Drs Harden and Leroy could have only received information about the status of these unpublished clinical trials from Parke-Davis.

168. Parke-Davis knew that proof of efficacy for monotherapy required successful completion of two clinical trials demonstrating Neurontin's efficacy. Clinical Study 945-82, a double blind, placebo-controlled study, was designed to be a pivotal study in support of monotherapy. But the results were negative, and failed to demonstrate that Neurontin was effective in treating seizures at doses up to 2400 mg/day. As early as November 1995, Parke-Davis knew that Clinical Trial 945-82 did not support a monotherapy indication. In addition to failing to establish monotherapy efficacy; Clinical Trial 945-82 also failed to establish a dose response at 600, 1200 and 2400 mg.

169. Parke-Davis also knew that another clinical trial, the Eastern European pilot study 945-177 (an extension of the 945-77 protocol) failed to establish dose differentiation and statistically significant efficacy. Parke-Davis did not intend to publish the results of 945-177, nor did they intend to publish the combined results of 945-77 and 945-177.

170. On September 13, 1996, Parke-Davis submitted a supplemental NDA to approve Neurontin as monotherapy for partial seizures. The FDA determined the application to be non-approvable on August 26, 1997 because of insufficiency of evidence of Neurontin's effectiveness. The FDA noted that Clinical Study 945-82 failed to yield evidence of effectiveness. Parke-Davis did not make public that its application for monotherapy had been denied. Representative events at which the Off-Label Promotion Enterprise continued to make presentations that Neurontin was effective for monotherapy without disclosing that the FDA had denied its application for a monotherapy indication included, but are not limited to:

Advisory Board Meeting at the Hyatt Regency Hotel	March 29, 2000	San Antonio, TX
Monotherapy Speakers Bureau Meeting at the La	September 1997	Palm Springs, CA

Quinta Resort

171. Although Parke-Davis sales representatives were not supposed to make representations about Neurontin's use for monotherapy, their sales representatives routinely made false statements concerning Neurontin's utility as a monotherapy agent. Plaintiffs were only able to obtain evidence of such statement for a limited time period between 1995 and 1997, but are aware of "verbatim" reports that exist for the last several years. Upon information and belief, review of recent verbatim reports will demonstrate that similar statement were regularly made by the Defendants' sales forces from 1999 through 2004. Representative statements made to physicians include:

- In January 1997, a Parke-Davis sales representative falsely stated that Neurontin was "Excellent first line [monotherapy] or add-on prescription for seizures."
- In a 1998 event, Parke-Davis falsely stated that Neurontin "Is effective as monotherapy."
- In October 1995, a Parke-Davis sales representative falsely stated that Neurontin's indicated use was "Soon to be monotherapy."

In June 1998, after the FDA had already rejected the monotherapy indication and Parke-Davis had abandoned pursuing approval for monotherapy, a Parke-Davis sales representative stated that Neurontin was "moving toward monotherapy indication in seizures."

172. In a Parke-Davis marketing event later in 1998, Parke-Davis went so far as to state that Neurontin was "now approved as monotherapy for seizures."

9. <u>Representations Regarding Migraine</u>

173. Parke-Davis knew that there was no pre-clinical rationale that would support the use of Neurontin in migraine prophylaxis.

174. Parke-Davis conducted a 12-week migraine prophylaxis study in Europe during the late 1980's that revealed no statistically significant difference in migraine attack frequency between placebo and 900 mg of Neurontin therapy.

175. In addition to the failed European migraine trial, Parke-Davis knew of several reports of negative results of Neurontin for migraine use, including reports from Dr. Seymour Solomon, Director of the Headache Unit at Montefiore Medical Center; Dr. John Rothrock, Chairman of the Department of Neurology at University of Alabama; Dr. Kenneth Michael Anthony Welch, Professor of Clinical Neurology at the University of Michigan; and Dr. Fred Michael Cutrer, Department of Neurology at Massachusetts General Hospital.

176. Parke-Davis never disclosed the negative European trial on migraine to any persons outside of the company, and the negative results were never published.

177. On May 25, 1996, Parke-Davis held an advisory board meeting to discuss "Gabapentin in the Management of Migraine." Parke-Davis's principal investigator for Neurontin and migraine chaired the meeting, and there were several other physicians in attendance. There were also several Parke-Davis employees in attendance, including the author of the marketing assessment, John Boris, who was aware of the failed European clinical trial. Vendor participant AMM/Adelphi ran the meeting. The purpose of the meeting was to discuss the knowledge of Neurontin's possible utility in the area of migraine and to solicit feedback on the development of clinical trials.

178. At the advisory board meeting, Parke-Davis suppressed any reference to the failed migraine study of the late 1980s. Leslie Magnus-Miller, Parke-Davis's Medical Affairs Director was directly asked, "But do you have any data [relating to Neurontin and migraine]?" Dr. Magnus-Miller responded: "We didn't…No, not really, because we didn't capture headache

baseline." Edda Guerrero added: "Unfortunately we did not, not even in monotherapy I think. Right?" John Boris did not correct this misstatement. Parke-Davis also failed to mention that there was "no established preclinical rational that would support the use of Neurontin in migraine prophylaxis."

179. Thereafter, pursuant to marketing strategies and tactics developed by Parke-Davis and the Off-Label Promotion Enterprise, the Off-Label Promotion Enterprise regularly presented programs in which physician participants touted Neurontin as being effective for the treatment of migraine. Events where such presentations were made include, but were not limit to, the following:

Advisory Board Meeting at the Hyatt Regency Hotel	March 29, 2000	San Antonio, TX
Gabapentin in the Management of Migraine	May 25, 1996	Short Hills, NY

180. Such statements were false and misleading. In these presentations, Parke-Davis failed to inform physician participants of the failed migraine trial or the negative anecdotal evidence it received from its own advisory board physicians. It also failed to inform physicians that there was no established rationale that would support the use of Neurontin for migraine and no clinical trial evidence. Defendants' failure to provide this information violated their duty of providing fair and balanced information and made any prior statements about Neurontin's use for migraine false and misleading.

181. Although Parke-Davis's sales representatives were not supposed to make representations about Neurontin's use for migraine, their sales representatives routinely made false statements regarding the utility of Neurontin in treating migraine. Plaintiffs were only able to obtain evidence of such statement for a limited time period between 1995 and 1997, but are aware of "verbatim" reports that exist for the last several years. Upon Information and belief, review of recent verbatim reports will demonstrate that similar statements were regularly made

by the Defendants' sales forces from 1999 through 2004. Representative statements made to physicians include a statement made by a Parke-Davis salesperson in August 1996 who stated "Effective in controlling …migraine headache."

10. False Statements About Other Indications

182. Neurontin is prescribed for hundreds of additional indications for which there is no scientific support and which are not approved by the FDA. Pursuant to marketing strategies and tactics developed by Parke-Davis and the Off-Label Promotion Enterprise, the Off-Label Promotion Enterprise regularly presented programs in which physician participants touted Neurontin as being effective for other conditions in addition to those described. Such statements were false and misleading, because there was no clinical trial evidence that Neurontin was effective for the treatment of any conditions other than adjunct therapy for partial seizures and post herpetic neuralgia. In these presentations, Parke-Davis failed to inform physician attendees that there was no established rationale that would support the use of Neurontin for conditions other that adjunct therapy for partial seizures and post-herpetic neuralgia. Defendants' failure to provide this information violated their duty of providing fair and balanced information and made any prior statements about Neurontin's use for conditions other tham adjunct therapy for partial seizures and post-herpetic neuralgia false and misleading.

11. Representations Regarding Dosages Above the FDA-Approved Maximum

183. Early in its experience in marketing Neurontin, Parke-Davis learned that many physicians did not consider the drug to be efficacious. Parke-Davis attempted to explain this lack of efficacy by trying to convince doctors that they had not given the patient sufficient medication. At an advisory board meeting, Parke- Davis stated it "therefore went on an

aggressive campaign to try to convince the doctors to push the dose of Neurontin up into the 2400 to 3600 mg range."

184. Evidence from clinical studies did not support Parke-Davis's marketing campaign to increase Neurontin dosages beyond the limit approved by the FDA was on the grounds of efficacy. Further, Parke-Davis knew of this lack of efficacy. As early as December 30, 1994, Parke-Davis knew that there was a lack of proportionality between the dose of gabapentin administered to subjects and the level absorbed. In other words, increasing the dosage of Neurontin does not necessarily mean that more Neurontin is actually absorbed by the body due to the manner it is excreted and the maximum levels that can accumulate.

185. As of November 14, 1995, Parke-Davis knew that clinical trials 945-82 did not show a dose related response. Patients who took 600 mg of Neurontin did not achieve any different results than patients who took 1200mg or 2400 mg. Such results were at odds with Parke-Davis's claim that the larger the dose, the better the effect.

186. Notwithstanding the failure of Clinical Trial 945-82 to exhibit a dose relationship, and notwithstanding the fact that the Core Marketing Team within Parke-Davis intended to initiate a nationwide campaign to convince physicians to increase dosing to 2400 mg/day (33% greater than the maximum dosage proven safe and effective), Parke-Davis made the deliberate decision that it would not initiate clinical trials to determine if higher dosages (1800mg to 3600mg) were effective in add-on therapy.

187. A second monotherapy clinical trial confirmed the lack of improved efficacy at higher dosages. In Clinical Trial 945-77, 900 mg/day Neurontin was found to be just as efficacious as Neurontin at 1800 mg/day. Defendants made a deliberate decision not to release the results of clinical trials that did not establish any dose differentiation.

188. Although Parke-Davis was routinely sponsoring programs that recommended that dosages be increased to as high as 4800 mg/day, Parke-Davis knew that it did not have sufficient toxicology data to prove that Neurontin was safe at dosages as high as 3600 mg.

189. During programs presented by the Off-Label Promotion Enterprise, physician participants routinely stated that dosages above the maximum approved by the FDA increased Neurontin's efficacy. For example, during the migraine advisory board meeting, Dr. Rafferty, a pre-clinical researcher from Parke-Davis, falsely stated the following: "The antiepileptic activity of gabapentin is quite dose dependent. Oh yeah." Parke-Davis was aware that its own clinical trial on Neurontin for epilepsy monotherapy had shown no dose-related difference in efficacy in doses ranging from 600 mg per day to 2400 mg per day. The negative findings of the monotherapy trial were not disclosed to the advisory board members.

190. At the "consultants" meeting in Jupiter Beach in April 1996, Dr. Longmire stated that: "most [patients] do better as you raise [the dose] higher." At the same presentation, and in other presentations, such as the Consultants' Meeting at the Boston Ritz Carlton, Dr. Longmire also stated that the only reason a patient who was actually taking his medication and not malingering would not receive any benefit from Neurontin was if he was not receiving a high enough dose. Neither Dr. Longmire nor the other Parke-Davis personnel present informed the physicians that Parke-Davis's own clinical trials established that there was no dose relationship.

191. At the same Consultants' Meeting, Dr. LeRoy stated: "we found that clinical usage requires [daily dosages of] 2200, 3200, 3600, up to what I think… again, as I said earlier, a limit of about 4800 milligrams." At a minimum, this statement was not fair and balanced in that it did not disclose any contrary findings about the lack of dose-related response,

including Parke-Davis's own outpatient study that failed to identify a dose response. It also did not disclose that Parke-Davis had no toxicology data establishing safety at doses this high.

192. At the Consultants' Meeting at the Boston Ritz- Carlton in May 1996, Dr. Longmire made false statements such as: "the problem with Neurontin in terms of real trigeminal neuralgia is that it has to be titrated upward. And when I say 1500 milligrams, that's the target starting dose. There are colleagues in the Huntsville area who, I have people on 5400 with no side effects." This statement was misleading for a number of reasons: it implied that Neurontin was effective for trigeminal neuralgia at higher-than-approved doses; it did not disclose side effects reported to Parke-Davis at higher level; it did not disclose the absence of toxicology data at these levels; it did not disclose there was no clinical data to support Neurontin's efficacy on trigeminal neuralgia; and it failed to disclose Parke-Davis's own clinical trials that questioned the existence of a dose relationship.

193. Notwithstanding the lack of toxicology data and clinical trial data supporting Neurontin's use at higher doses, attendees at Jupiter Beach were convinced that they should be prescribing Neurontin at amounts in excess of its labeling. One physician noted "(O)ne of the main messages that I got out of the speakers [that doctors haven't been pushing the dose up high enough]. (Inaudible) 4800 milligrams (Inaudible). And I've sort of gone to 24 and maybe a little higher and then stopped. To me, that was an important point (Inaudible) I'm not really pushing the drug enough."

194. Parke-Davis applied to the FDA to increase the effective dose range to include 3600 mg/day and to increase the maximum recommended dose to 4800 mg/day. On August 26, 1997, the FDA denied the application because there was no evidence that Neurontin was safe at such doses.

195. The FDA also informed Parke-Davis that if it did provide safety data, it could only obtain the labeling change if it further disclosed that "evidence from controlled trials fails to provide evidence that higher dose of Neurontin are more effective than those recommended".

196. Parke-Davis never disclosed that the FDA denied its request to increase the maximum approved dose of Neurontin, that the FDA had determined that Parke-Davis had not provided sufficient evidence of safety at higher doses, and that there was no clinical trial evidence that Neurontin was more effective at higher doses. Parke-Davis continued to market Neurontin at higher doses without these disclosures.

197. Notwithstanding the FDA's refusal to increase the maximum approved dosage of Neurontin and its finding that no clinical evidence supported Neurontin's efficacy at dosages greater 1800 mg per day, the Off-Label Promotion Enterprise presented numerous programs where physician participants asserted that Neurontin was effective and safe at dosages above 1800 mg. All such representations were false and misleading. Additionally, at these presentations the physician participants did not disclose the clinical trial evidence that demonstrated that there was no dose response above 1800 mg per day. Defendants' failure to provide this information was a violation of defendants' duties to provide fair and balanced information and made any prior representations about use of Neurontin at dosages greater than 1800 mg false and misleading. In addition to the events identified above, other events where these false and misleading statements were made include, but are not limited to, the following:

Advisory Board on Neurontin at the Royal Sonesta	February 4-6, 2000	New Orleans, LA
Merritt-Putnam Speakers Bureau Current Perspectives in the Understanding of Neurobehavioral Disorders at the Four Seasons Regent Beverly Wilshire	March 24-26, 2000	Beverly Hills, CA

Advisory Board Meeting at the Hyatt Regency Hotel March 29, 2000 San Antonio, TX

12. Representations Concerning Lack of Side Effects

198. Parke-Davis knew that there was a dose relationship between Neurontin and side effects. Clinical Trial 945-77 demonstrated that patients were three times more likely to have side effects at 1800 mg/day than at 900 mg/day.

199. Parke-Davis was aware that the January 1996 edition of Epilepsy reported behavioral side effects of gabapentin in seven children who received Neurontin as adjunctive therapy. The most troublesome behaviors were tantrums, aggression towards others, hyperactivity, and defiance.

200. Parke-Davis knew as of November 19, 1996 that high doses of gabapentin could lead to weight gain.

201. Parke-Davis also knew that, similar to other anti-epileptic drugs, patients on high doses of Neurontin had to be titrated down, or else they would suffer withdrawal symptom side effects.

202. At numerous events presented by the Off-Label Promotion Enterprise, physician participants informed physician attendees that Neurontin use at high levels did not cause side effects. For example, at the Jupiter Beach Consultants' Meeting in April 1996, Dr. Schachter stated: "Well, I don't think there's any data suggesting that there's any withdrawal syndrome from Neurontin at this point." At that time, Parke-Davis was aware of at least anecdotal reports of withdrawal syndrome and that Neurontin patients had to be tapered off Neurontin in much the same manner that they titrated up, but physician attendees were not informed of this information.

203. Similarly, at the Boston Ritz-Carlton Consultants Meeting in May 1996, Dr. Longmire falsely stated that adverse reactions tend to be idiosyncratic, and that they did not

seem to be dose-dependent. Again, the physician attendees were not informed of the medical evidence in Parke-Davis's possession that side effects were dose responsive. Defendants' failure to provide this information was a violation of defendants' duties to provide fair and balanced information and made any prior representations about Neurontin's propensity to induce side effects at dosages over 1800 mg /day false and misleading.

204. In every event presented by the Off-Label Promotion Enterprise, including but not limited to, every event identified in this Amended Complaint, participating physicians asserted that Neurontin had a low side effect profile and therefore there was little risk in using the drug for off-label, unapproved indications. This "fact" was one of Neurontin's largest selling points. Failure to provide a fair and balanced presentation of the side effects that were caused by Neurontin, especially at elevated doses, falsely implied that Neurontin was safe when prescribed for unapproved indications.

205. At every presentation concerning Neurontin's use for off-label indications, anecdotal evidence was presented to support Neurontin's lack of side effects. Upon information and belief, at none of the presentations, however, was anecdotal evidence presented of Neurontin's causation of debilitating side effects even though such evidence had been made known to Defendants. Defendants' intentional failure to provide a fair and balanced presentation of the anecdotal information concerning Neurontin's safety made their presentation false and misleading.

13. Misrepresentation of Promotional Nature of Events

206. As described above, all of the events presented by the Off-Label Promotion Enterprise were made to appear to the attendee physicians to be bona fide educational events where disinterested leading clinicians shared their knowledge and experience in an educational setting. In fact, these events were peer selling promotional events designed to

convince the attending physicians to prescribe Neurontin. Important facts that would have warned the attendee physicians that they were attending a promotional event for a drug company were concealed. These included the following facts:

- That virtually all of the publications and/or studies that purported to support Neurontin's use for off-label indications were funded by the Defendants;
- That virtually all of the studies that purported to support Neurontin's use for off-label indications had not been initiated by the physicians who were credited as authors, but by the Defendants and other members of the Off-Label Promotion Enterprise pursuant to a corporate marketing plan designed to increase off-label sales;
- That studies existed that found that Neurontin was not effective for off-label uses, but Defendants had deliberately refused to publish or publicize such studies; and
- That the participating doctors who were conducting the peer selling had been paid substantial subsidies to use Neurontin on their patients or in reward for their recommending Neurontin's use for off-label indications.

At all events that appeared to be continuing medical education programs, the members of the Off-Label Promotion Enterprise described Defendants' contribution as merely the provision of an "unrestricted" grant. For the reasons set forth above, the grants provided by Defendants were not unrestricted but instead were conditioned on Defendants' receipt of a comprehensive program that advocated Neurontin's use for off-label indications and displayed the drug in the most favorable light available. Hiding Defendants' control of the content of the program and misrepresenting its financial support as an "unrestricted" grant were materially false statements that concealed the promotional nature of the programs. Had the attending physicians known the programs were outright promotion they would have viewed the presentations with

greater skepticism and doubted the claims of the participating physicians that Neurontin was effective for the off-label indications.

F. Defendants' Use of Medical Liaisons to Promote Off-Label Uses for Neurontin

207. Defendants' normal sales force was not permitted to promote off-label uses of Neurontin to its physician customers. The FDA, however, permitted drug company representatives to provide balanced, truthful information regarding off-label usage if specifically requested by a physician and if there were no attempt to solicit such information by the drug company. Starting in 1995, Defendants hired medical liaisons that were ostensibly supposed to provide this information to physicians who had requested it. Medical liaisons were also supposed to coordinate funding of studies and clinical trials with interested physicians.

208. In fact, the medical liaison program was part of the same marketing plan and marketing tactics that promoted Neurontin off-label through the Off-Label Promotion Enterprise. As another component of the marketing plans produced by the Neurontin Extended Disease Team, Defendants trained medical liaisons to solicit requests for off-label information aggressively from physicians. Having opened this door to a conversation about Neurontin, medical liaisons would then engage in full-scale promotion of Neurontin's off-label uses, including by providing non-scientific, anecdotal information designed to convince physicians that off-label usage of Neurontin was safe and effective. In effect, Parke-Davis used the medical liaisons as a surrogate sales force who marketed Neurontin for off-label uses. Indeed, medical liaisons were selected and promoted based on their ability to sell, and sales training was encouraged.

209. In their presentations to physicians, medical liaisons were trained to provide the same false information described above regarding the efficacy of Neurontin for off-

label uses. Similarly, the medical liaisons did not provide all information necessary to make their prior disclosures not false and misleading, including not limited to, failing to inform the physicians with whom they met that there was no scientific evidence to support Neurontin's use for non-approved indications (other than post-herpetic neuralgia), failing to disclose negative clinical trial evidence and failing to disclose negative anecdotal evidence.

G. Parke-Davis's Systematic Payments to Doctors for the Purpose of Increasing Neurontin Prescriptions

210. Customarily, drug companies such as Defendants inform physicians of their new products and those products' uses through office meetings at the physicians' offices by the drug companies' sales force. Defendants could not use this practice to inform physicians of unapproved uses for Neurontin because it could not use its traditional sales force to promote for off-label uses. Defendants had to devise a way to get the doctors to hear their message in other forums. They also had to induce physicians to become part of the Off-Label Promotion Enterprise and recommend Neurontin for off-label uses. Defendants elected to pay kickbacks and otherwise provide participant and attendee physicians with items of substantial value to induce them to listen to the off-label marketing pitch, to prescribe Neurontin, and to recommend Neurontin to other physicians. Defendants also paid kickbacks and provided other items of value to reward physicians for having prescribed Neurontin. Defendants made thousands of payments for these purposes in violation of federal kickback laws, and state commercial bribery laws. Many of these payments were technically made by the vendor participants, but Defendants provided the funds for all of the payments, knowing that these payments would be made to induce physicians to change their prescribing behavior regardless of their fiduciary duties to their patients, their practices and their treatment networks.

211. Plaintiffs have already described how Defendants paid physician participants substantial fees (as well as extensive travel benefits) for agreeing to engage in peer to peer selling on behalf of off-label Neurontin. Plaintiffs have also described how Defendants induced physicians to use Neurontin on their patients or rewarded physicians for having used Neurontin on their patients by paying them for "studies" that had minimal, if any, scientific value or paying them to use their names on ghost written articles. Such payments and provision of items of value were expressly performed for the purpose of influencing the recipients' conduct.

212. Additionally, Defendants provided payments and items of substantial value to physicians that were the targets of the Off-Label Promotion Enterprise. The Off-Label Promotion Enterprise routinely provided substantial items of value to these physicians to attend events at which off-label uses of Neurontin were being promoted. The following describes various ways Defendants funneled bribes to physicians.

1. Consultants' Meetings

213. The Off-Label Promotion Enterprise regularly convened "consultants'" meetings as a method for funneling cash and other benefits to physicians in exchange for hearing extensive presentations on the use of Neurontin for off-label purposes. There was no attempt at these meetings, which were often held in luxury resorts, to conform to the requirements of a CME meeting. Instead, Defendants and the vendor participants structured the meeting as if the attendee doctors had been retained by Parke-Davis to advise the company on a strategic issue. The "consultants" were not chosen to attend based on particular skills or expertise the physician possessed, but because of the potential to write Neurontin prescriptions. Only "high decile," i.e., high prescribing, physicians were selected for these junkets.

214. The vendor participants arranged for the doctors' transportation, lodging and entertainment and sometimes (but not always) had the doctors sign sham consulting

agreements. At these meetings Defendants' employees or doctor participants would give the "consultants" substantial presentations relating to Neurontin, particularly its use for unapproved indications. At some conferences, the vendor participant or Defendants intentionally posed questions to the speakers about off-label use to insure the attendees were exposed to such information.

215. The consultants' meetings were not held – and the "consultants" were not paid – for the purpose of providing Defendants with expert, independent advice. Defendants in many cases did not even record the "advice" provided by its "consultants," and what little advice was collected was never acted upon or reviewed. Rather, Defendants routinely analyzed whether consultants' meetings successfully influenced physicians' prescription writing practices. At some meetings, the "consultants" were directly asked if they would write more Neurontin prescriptions as a result of the meeting. Such a question would have been irrelevant if the actual purpose of the meeting was to receive the "consultants'" advice. Defendants also routinely tracked consultants' Neurontin prescription writing practices after these meetings. Using market data purchased from third parties, Defendants analyzed whether the doctors they had paid had in fact written more Neurontin prescriptions after the meeting. Again, such data was only relevant if the real purpose of the payments was to influence the doctors to order more Neurontin.

216. A typical "consultants'" meeting was held in Jupiter Beach, Florida, for neurologists from the Northeast CBU during the weekend of April 19-21, 1996. The "consultants" selected for this meeting were not chosen on the basis of their consulting acumen, but because of their potential to write Neurontin prescriptions. In a memorandum announcing the event to Defendants' personnel, the Neurontin Marketing Team acknowledged that in order to target neurologists with the greatest potential for writing Neurontin prescriptions, sales

personnel must select potential attendees from a list of the top prescription writers for anti-epileptic drugs in the Northeast. Only persons who fell within this desirable demographic were to be invited.

217. Qualifying physicians were given a round-trip airfare to Florida (worth $800.00), two nights' accommodations (worth $340.00), free meals and entertainment, ground transportation and a "consultant's fee" of $250.00. Ample time was provided so that the Parke-Davis consultants could enjoy the beach resort. The value of the junket was approximately $2,000.00 per physician.

218. The Jupiter Beach consultants' meeting included two half days of presentations by Defendants relating to Neurontin, including extensive presentations relating to off-label uses. Technically, the Proworx division of Cline Davis produced the event; however, Defendants designed, monitored, and approved all aspects of the presentation. They selected the speakers, picked the presentation topics, and previewed the content of the presentations to make sure that they were acceptable. Defendants paid all expenses relating to the consultants' meeting, including all payments to the attendees and the presenters, all travel, accommodation, meals and entertainment expenses, all presentation expenses, all expenses and fees incurred by Proworx, and the substantial fees paid to the participant physicians. Notwithstanding the FDA's prohibition regarding the provision of promotional materials relating to off-label uses, Defendants provided written abstracts of the presentations that detailed off-label use of Neurontin to each of their "consultants."

219. Defendants made no effort to obtain professional advice at Jupiter Beach from the "consultants" Defendants wined, dined, and entertained during the weekend. A follow-up memorandum to Defendants' marketing officials noted that "the participants were delivered a

hard hitting message about Neurontin," and emphasized that the participants were encouraged to use Neurontin at higher doses. More importantly, after the conference Defendants generated "trending worksheets" listing the doctors who attended the consultants' meeting. These worksheets enabled Defendants to track Neurontin prescription habits of the attendees before and after the consultant's meetings to determine if these "high writing" prescribers wrote more Neurontin scripts after the conference. Persuading these heavy prescribers to order more Neurontin for their patients was, in fact, the sole purpose of the Jupiter Beach junket.

220. Jupiter Beach was not unique. Defendants in conjunction with the vendor participants hosted dozens of consultants' meetings between late 1995 and 1997 in which the "consultants" received payments and gratuities, as well as presentations on off-label Neurontin use designed to change the physicians' prescription writing habits. Comparable consultants' meetings included, but were not limited to, the following:

Topic	Location	Date
Mastering Epilepsy	La Costa Resort, CA	July 20-23, 1995
Mastering Epilepsy	Santa Fe, NM	Nov. 16-19, 1996
Neurontin Consultants Conference	Marco Island, FL	Feb. 2-4, 1996
Pediatric Epilepsy	Hutchinson Island, FL	Feb. 9-11, 1996
Mastering Epilepsy Science	Walt Disney World, FL	Feb. 22-25, 1996
Pediatric Epilepsy	Hutchinson Island, FL	March 8-10, 1996
Mastering Epilepsy	Aspen, CO	April 18-21, 1996
Affective Disorders in Psychiatry	Marco Island, FL	April 20, 1996
Affective Disorder Consultants Conference	Southern Pines, NC	April 27, 1996
Neuropathic Pain Conference	Palm Beach, FL	May 11, 1996
Regional Consultants Conference	Boston, MA	May 10-11, 1996
Epilepsy Management Advisors Meeting	La Jolla, CA	June 21-23, 1996
Epilepsy Management	Rancho Bernardo, CA	June 28-30, 1996
Use of Anti-Convulsants in Psychiatric Disorders	Short Hills, NJ	Oct. 18-19, 1996
Non-Epileptic Uses of Neurontin	Longboat Key, FL	Nov. 6, 1996
Neurological Conditions Conference	Atlanta, GA	Sept. 27-28, 1997

221. Other consultants' meetings took place in Charleston, SC, Coconut Grove, FL, Naples, FL, Memphis, TN, Louisville, KY, Washington, DC, Aspen, CO, and other places. Hundreds, if not thousands, of physicians received kickbacks to attend these events.

222. Not all payments to consultants were made at conferences as elaborate as Jupiter Beach. Many consultants' meetings consisted of lavish dinners at local restaurants. The emphasis on these meetings was also on off-label uses, and Defendants paid $200 "honorariums" to the physicians who did nothing for the payment except show up. At none of the events did the consultants provide legitimate consultation to Defendants, but at all of the events the "consultants" were encouraged to increase their Neurontin prescriptions.

2. Medical Education Seminars

223. Another format where Defendants paid kickbacks to physicians to hear off-label promotion of Neurontin were programs billed as Continuing Medical Education seminars (CME). These conferences and seminars were set up to appear to qualify for the exception to the FDA's off-label rules that permitted physicians to learn about off-label uses of pharmaceuticals at independent seminars. However, these were not bona fide educational seminars. The reasons they were not bona fide are described in more detail above, but include the following: that Defendants designed and approved the programs; that Defendants hand-picked the speakers; that Defendants approved the presentations; that Defendants selected the attendees based on their ability and willingness to prescribe high quantities of Neurontin; and Defendants monitored the prescribing patterns of the physicians who attended these conferences. All of this was done to insure the purpose of the conference–to increase writing of Neurontin prescriptions–was achieved. Follow-up reports to marketing executives at Parke-Davis highlighted that the attendees received presentations regarding off-label marketing and recommendations for dosages larger than those labeled effective by the FDA. These memoranda

also reported to senior executives the pledges made by attendees to order more Neurontin for their patients.

224. For some seminars, high prescription-writing physicians were selected to receive junkets comparable to those Parke-Davis provided to the attendees of the Jupiter Beach consultants' meetings. Others were less lavish, but physicians still received free tuition, free accommodations, free meals, and cash. Frequently Defendants' CME seminars were accredited by continuing medical education organizations, which meant that the physicians taking advantage of Defendants' junkets did not have to pay tuition or spend additional time to fulfill their continuing medical education licensure requirements by attending truly independent medical education programs.

225. Representative CME programs sponsored by Parke-Davis where it paid extensive kickbacks to attending physicians, included, but are not limited to, the following:

Seminar	Location	Date
Merritt-Putnam Epilepsy Postgraduate Course		Jan. 19, 1996
Merritt-Putnam Seminar	Chicago, IL	Jan. 26, 1996
New Frontiers in Anti-Epileptic Drug Use	California	Sept.-Oct. 1996
Diabetic Neuropathy	Boston, MA	June 22-24, 1997
Merritt Putnam Symposium	Key Biscayne, FL	September 11, 1997
Merritt Putnam Conference on Monotherapy	Palm Springs, CA	Sept. 19, 1997
Merritt-Putnam Conference on Monotherapy	St. Louis, MO	Oct. 3, 1997
Merritt-Putnam Symposium	Boston, MA	Dec. 5, 1997

3. Grants and "Studies"

226. Defendants also made outright payments, in the form of grants, to reward demonstrated Neurontin believers and advocates. Defendants' sales managers identified key doctors who actively prescribed Neurontin or programs that were willing to host Neurontin speakers and encouraged such persons or programs to obtain "educational grants" from them. Under this program of kickbacks Defendants paid:

- $2,000.00 to Berge Ninmpolan, MD, "a great Neurontin believer," to attend a neurology seminar in San Francisco, in March 1996.
- $1,000.00 to the University of Texas at Houston Department of Neurology to host a symposium where presentations would be made regarding successful off-label treatment with Neurontin.
- $3,000.00 to the University of Texas Medical School to host a conference in August 1996 at which a well-known specialist in epilepsy, who prescribed Neurontin, would attend.
- $4,000.00 to pay for a neurologist from the University of Texas at San Antonio to attend the American Epilepsy Society Conference in December 1996, a conference at which Parke-Davis was presenting extensive documentation on off-label uses for Neurontin.
- $2,500.00 to the University of Texas in Houston to bring Dr. B.J. Wilder to the campus to hold a seminar. Dr. Wilder was one of Neurontin's biggest boosters for off-label indications and had been paid tens of thousands of dollars to promote Neurontin's off-label uses for Parke-Davis across the country.
- $2,500.00 in June 1996 to pay for representatives from the University of Pennsylvania Medical Center to attend a conference in Saint Petersburg, Russia on the utilization of anti-epileptic drugs, including Neurontin.
- $5,000.00 in December 1996 to Dr. Alan B. Ettinger, of Stonybrook, N.Y., a physician who had informed Parke-Davis that he was interested in possibly doing research in Neurontin and maintained a database of patients who were treated with Neurontin.
- $500 to Bruce Ehrenberg, of Boston, MA, a leading speaker for Parke-Davis regarding off-label use of Neurontin, to attend a conference in China.

- $1000 to Israel Abrams, M.D., Paul C. Marshall, M.D., Beth Rosten, M.D. and Spencer G. Weig, of Worcester MA, for educational programs in February 1996. According to the local Parke Davis representative requesting the grant, "much of the Neurontin success in Worcester has been attributed to . . . the 4 pedi[atric] epileptologists below."
- $1,400 to Dr. Ahmad Beydoun of Ann Arbor, MI for post-graduate training in March 1996. This grant was processed on a quick turnaround, the Parke-Davis representative noting "I realize that this is a very short time line; however, Dr. Beydoun is a very important customer."
- $1,500 to Jim McAuley, R.Ph, Ph.D. for educational materials relating to epilepsy. Parke-Davis decided to provide the funds because McAuley was an advocate of Neurontin and he was important in getting another Parke-Davis drug, Cerebyx, accepted on the formulary for Ohio State University.
- A grant in an unknown amount to University Hospital in Cleveland in exchange for hosting programs regarding Neurontin's use in treating neuropathic pain at conferences specifically devoted to obtaining referrals from other doctors.

227. These grants, and others, were charged to the Neurontin marketing budget. Each of these grants were made solely because an individual receiving the money was a large Neurontin supporter or was going to host a program where a well known Neurontin supporter would recommend that other physicians increase their prescriptions of Neurontin. Each of these grant awards constituted a reward or kickback for the recipient's advocacy of Neurontin.

228. Defendants' medical liaisons informed leading Neurontin prescribers that significant advocacy for Neurontin would result in the payment of large grants. These studies did not involve significant work for the physicians. Often times they required little more than

collating and summarizing office notes or records. Oftentimes, the physicians contributed nothing at all to the study because Defendants frequently hired technical writers to write the articles for which the "authors" had been given grants.

229. Defendants were aware that these articles and studies provided minimal scientific benefit. In a letter to the FDA in June 1997, Defendants submitted a list of "studies relating to pain, pain syndromes, and psychiatric disorders" but failed to include any of the studies described below. Defendants intentionally neglected to report these "studies" to the FDA because they knew the funded "research" had no scientific value and would not be deemed a scientific trial by the FDA. Payments Defendants made for these "studies" included, but were not limited to, the following:

Funded Project	Payee	Payment
Statistical Analysis of Patients Treated With Neurontin For Pain Reduction of Sympathetically Medicated Pain and Sudomotor Function	Hans Hansen, M.D., Statesville, N.C.	$7,000.00
	David R. Longmire, M.D., Russellville, AL	$7,000.00
Data entry for Neurontin and Pain Analysis	David Meyer, M.D.	[amount unknown]
Trial of Neurontin for distal symmetric polyneuropathy associated with AIDS	Joseph Weissman, M.D., Atlanta, GA	$20,000.00
Neurontin for neuropathic pain in chronic pain syndromes	Lavern Brett, M.D., Washington, D.C.	$25,000.00
Retrospective chart analysis of Neurontin use with bipolar disorder patients	Ralph S. Rybeck, M.D.	$5,000.00
Retrospective Analysis of Neurontin in the treatment of pain	David R. Longmire, M.D., Russellville, AL	$2,000.00
Retrospective Analysis of Neurontin in the treatment of chronic pain	Don Schanz, D.O., Traverse City, MI	$8,000.00
Case histories relating to use of Neurontin as an adjuvant analgesic	Elizabeth J. Narcessian, M.D., W. Orange, N.J.	$4,000.00

Plaintiffs have only been able to review limited records of the Defendants but have reason to believe that other payments were made to physicians for other "studies" of questionable scientific credibility.

230. One particularly large study conducted by Parke-Davis served as yet another engine to reward physicians financially for prescribing Neurontin. In 1995 and 1996 Parke-Davis conducted an enormous Phase IV trial known as STEPS. Although STEPS took the form of a research clinical trial, it was, in fact, a marketing ploy designed to induce neurologists to become comfortable prescribing Neurontin at a far higher dose than indicated in the FDA-approved labeling. While most clinical studies have a limited numbers of investigators treating a number of patients qualified for the study, the STEPS protocol called for over 1,200 "investigators" to enroll only a few patients each. The participating physicians were instructed to titrate their patients to higher-than-labeled dosages of Neurontin to demonstrate that patients could tolerate high dosages of the drug. Rewarding physicians for prescribing high doses of Neurontin was another way to increase Neurontin sales, as higher per-patient dosages increased the amount of Neurontin sold. Additionally, the STEPS study was also designed to habituate physicians to place non-study patients on Neurontin on doses higher than those found effective in the clinical trials monitored by the FDA.

231. Physicians enrolling in the STEPS study were paid for agreeing to participate in the study and for every patient enrolled. At the conclusion of the study, Parke-Davis offered each of the 1,200 investigators additional cash for each patient the doctor kept on Neurontin after the study ended. These payments constituted kickbacks, since each participating doctor was expressly paid for writing Neurontin prescriptions for their patients and the payment was offered expressly to change the physicians' behavior.

232. Defendants were well aware that federal law prohibits the kickbacks described above and that their payment did not comply with the AMA's guidelines for payments to physicians. Such payments also violated state commercial bribery statutes which prohibit

offering anything of value to a fiduciary for the purpose of altering the fiduciaries' conduct towards those to whom he owes fiduciary duties. Physicians owe fiduciary duties to their patients to prescribe what is in the best interest of the patient, not what is in the pecuniary interest of the physician. Additionally, those physician who are part of medical networks that manage patients' care or practices which have capitated patients' treatment owe additional fiduciary duties to the networks and/or practices to insure they treat patients in a cost effective manner and not make prescribing decisions that enrich the physician at the expense of the organization which ultimately pays for such treatment.

233. In 1997, in the wake of an investigation by the FDA, Parke-Davis conducted a review of its marketing practices in light of existing Medicaid kickback regulations. As a result of that review, Parke-Davis determined that none of the programs described above should have been pursued. Parke-Davis issued guidelines to comply with Federal regulations, which essentially prohibited each of the programs described above. Nonetheless, the payments to physicians for the off-label marketing of Neurontin did not cease, and the programs continued at least until 2001, the last year for which Plaintiffs have been able to view documentation. Because such payments continued after the merger of Warner-Lambert with Pfizer and off-label use of Neurontin continued to grow in the absence of scientific proof, upon information and belief Plaintiffs allege such payments continued up until Warner-Lambert's guilty plea on May 13, 2004, and its execution of a corporate integrity agreement with the United States. Defendants were well aware that federal law prohibits such kickbacks.

H. Illegal Off-Label Promotion Has Continued As Has The Continuing Impact Of The Earlier Misconduct

234. As a result of the conduct described above, physicians received large amounts of false information and therefore continue to prescribe Neurontin for off-label uses for which there is no reliable scientific support.

235. Upon information and belief, Pfizer has routinely marketed Neurontin for off-label indications up until May of 2004, regardless of FDA limitations on the approved use of the particular product. The staggering growth of Neurontin sales for non-approved FDA use highlights this continuing course of conduct. From 1995 to 2003, Neurontin's sales soared from $97.5 million to nearly $2.7 billion. With no reliable scientific studies supporting off-label uses, and with 90% of all prescriptions for Neurontin written for such uses, it is reasonable to infer that this explosion in sales stems from past and continuing promotional efforts by Defendants. Further, since 1999 off-label usage predominates in the precise areas where Defendants focused their unlawful marketing efforts, i.e., as treatments for bipolar disorder, peripheral neuropathy, and migraine headaches.

236. Various therapeutic substitutes compete for market share for the indications which have resulted in the largest percentage of off-label Neurontin prescriptions, and many of these competing treatments have been legally supported by aggressive marketing efforts. If any company discontinued their promotional efforts in any of these treatment areas, they would likely suffer significant losses within that area. Neurontin has suffered no such drop in sales. Upon information and belief, as a result of Defendants' and the Off-Label Promotion Enterprise's illegal promotional activities, physicians have and continue to prescribe Neurontin to tens of thousands of patients who are in need of an effective treatment.

237. A July 1, 2002, letter from Dr. Lisa Stockbridge of the Department of Health & Human Services ("HHS") confirms that Defendants continued as of that date to engage in off-label promotional efforts. Dr. Stockbridge notified Pfizer that certain of its marketing practices are "in violation of the Federal Food, Drug and Cosmetic Act . . . because [Pfizer] makes representations about Neurontin that are false and misleading." In particular, HHS determined that Pfizer marketing materials suggested that the mechanism of action of Neurontin had been established when it was not appropriate to make such a claim, and that materials suggested that Neurontin could be used as monotherapy when it was only appropriate to indicate Neurontin as adjunctive therapy in the treatment of partial seizures. The Stockbridge letter determined that Pfizer's marketing materials were misleading and ordered immediate discontinuation of their use. The marketing practices found to be misleading by HHS are consistent with those routinely engaged in by the Off-Label Promotion Enterprise under Parke-Davis's and then Pfizer's direction.

238. Citations in a medical reference-text for Neurontin, as of the third quarter of 2002, confirm that there is no basis in the published scientific literature for the use of Neurontin to treat the following conditions: alcohol detoxification/alcohol withdrawal syndrome, ALS, antidepressant-induced bruxism, anxiety disorder, attention deficit disorder/attention deficit and hyperactivity disorder, behavior problems-dementia related, behavior dyscontrol, dipolar disorder, brachioradial pruritis, back pain, Charles Bonnet syndrome, ciguatera poisoning, cluster headache, cocaine dependency, diabetic peripheral neuropathy, depression, dosages in excess of 1800 mg per day, dystonia, essential tremor, failed back surgery syndrome, headache (SUNCT), headache, hemifacial spasm, hiccups, Lesch-Nyhan syndrome, mania, migraine prophylaxis, menopausal hot flashes, mood stabilization, multiple sclerosis

complications, myalgias taxane induced neuropathic pain syndromes, neuropathic cancer pain, HIV-related neuropathy, nicotine withdrawal, nystagmus, obsessive-compulsive disorder, orthostatis tremor, pain-postpoliomyelitis pain, pain-RSD, pain disorder, partial seizures-monotherapy, partial seizures-pediatric, partial seizures-refractory, phantom limb syndrome, postherpetic neuralgia, restless les syndrome, trigeminal neuralgia, seizures - acute intermittent prophyria, seizures - brain tumor-induced, seizures - clozapine-induced, seizures - generalized, seizures - status epilepticus, schizophrenia, social phobia, spasticity, or any other indication other than the partial seizures-adjunctive therapy, partial seizures-pediatric, postherpetic neuralgia, and diabetic peripheral neuropathy.

239. Any representations by any agent, employee, or person hired by Parke-Davis that, as of the third quarter of 2002, scientific evidence supported Neurontin's use, or was effective for use, for the conditions listed in the preceding paragraph was misleading. Upon information and belief, Defendants' employees made representations that Neurontin was an appropriate treatment for some or all of these conditions.

I. Government and Other Actions Concerning Defendants' Off-Label Promotion

240. Dr. David Franklin initiated a qui tam action on behalf of the United States against the Parke-Davis division of Warner-Lambert in 1996. He alleged that Defendants knowing promotion of Neurontin for off-label used caused false claims to be presented to the United States for prescription sales that were ineligible for Medicaid Reimbursement and also caused by the payment of kickbacks in violation of the Medicaid anti-kickback provisions, 31 U.S.C. § 3729. The federal court unsealed Dr. Franklin's original complaint in January, 2000. In April 2002, the Court unsealed Dr. Franklin's amended complaint, which, for the first time, contained details of Defendants' off-label promotion. In April 2003, Dr. Franklin filed an

opposition to a motion for summary judgment that unsealed numerous documents revealing the existence and operation of the Off-Label Promotion Enterprise.

241. As a result of the filing of the Franklin qui tam lawsuit, the United States Attorney for the District of Massachusetts conducted an investigation and ultimately filed a criminal information against Warner-Lambert. On May 13, 1994, the company pleaded guilty to several violations of the Food, Drug and Cosmetic Act, 21 U.S.C. §§331(a), 331(d), 333(a), 352(f)(1), and 355. Warner-Lambert was fined $240 million and agreed to cease and desist its pattern of misconduct. The United States Attorney for the District of Massachusetts also opened a civil investigation regarding Defendants' marketing practices with regard to Neurontin.

242. Various state attorneys general also commenced investigations of Defendants Off-Label marketing practices concerning Neurontin. One group of state attorneys general and the National Association Of Medicaid Fraud Control Units opened civil and criminal investigations against Warner-Lambert for Medicaid fraud. A second group of attorneys general investigated violations of state consumer protection laws that occurred when Warner-Lambert promoted Neurontin for various off-label uses.

243. The qui tam, federal civil investigation and state attorneys general investigations settled at the same time. As part of an omnibus civil settlement, Defendants paid $ 190 million to resolve the civil claims and investigations pending against them.

244. As part of the Omnibus civil settlement, Defendants and the states attorneys general entered into The Assurance of Voluntary Compliance. The Voluntary Compliance explicitly provided that claims brought by individual consumers and entities were excluded from the omnibus civil settlement.

V. FRAUDULENT CONCEALMENT AND TOLLING OF STATUTES OF LIMITATIONS

245. In order to avoid sanction and regulation by the FDA, Defendants' off-label marketing scheme depended on their concealment of their involvement in off-label promotion of Neurontin. Indeed, the Off-Label Promotion Enterprise was created precisely to make it appear to the public that the Defendants did not have a hand in any discussions of off-label use. Additionally, as described above, Defendants had the Off-Label Promotion Enterprise perform off-label promotion in the semblance of legitimate consultants' meetings, continuing education seminars, journal articles and medical education events. Also as described above, Defendants' involvement was hidden because Defendants hid their financial connections between the participating physicians and used the vendor participants as payment intermediaries. These activities and others described above concealed Defendants' off-label promotional activities and Plaintiffs could not have discovered the scheme alleged herein earlier in the exercise of reasonable diligence. Much of the scheme to this day remains concealed by Defendants.

246. The earliest Plaintiffs could have reasonably become aware of the off-label promotion scheme was in May, 2003 when the details of Defendants' interactions with the other participants in the Off-Label Promotion Enterprise were disclosed through Dr. Franklin's filing of previously sealed materials in opposition to Defendants' motion for summary judgment in the qui tam action. Alternatively, Plaintiffs in the exercise of reasonable diligence could not have learned of the off-label promotion scheme until some of the details were disclosed when the Court unsealed Dr. Franklin's Amended Complaint in the qui tam case in April 2002.

247. Any applicable statutes of limitations have been tolled by Defendants' knowing and active concealment and denial of the facts alleged herein. Plaintiffs and members

of the Class have been kept in ignorance of vital information essential to the pursuit of these clams, without any fault or lack of diligence on their part. Plaintiffs and members of the Class could not reasonably have discovered the fraudulent nature of Defendants' conduct. Accordingly, Defendants are estopped from relying on any statute of limitations to defeat any of Plaintiffs' or the Class' claims.

VI. DEFENDANTS' MOTIVES AND CAUSATION OF DAMAGE

248. Defendants' motive in creating and operating the fraudulent scheme and RICO Enterprises described herein was fraudulently to obtain additional revenues from the marketing and sale of Neurontin.

249. The fraudulent scheme was designed to, and did, cause Plaintiffs and the Class to pay for Neurontin prescriptions to treat conditions for which the drug is not effective. Patients including the individual Plaintiffs, the individual class members, and individual Plaintiffs whose prescription drug charges were paid by TPP class members, and who were prescribed the drug for non-approved uses received no greater relief from, or treatment of, their medical conditions than they would have received from a placebo. The fraudulent scheme also caused Plaintiffs and the Class to pay for Neurontin prescriptions to treat non-FDA approved conditions for which it was not effective. In the absence of Defendants' improper conduct, Plaintiffs and the Class would not have paid for such Neurontin prescriptions.

VII. USE OF THE MAILS AND WIRES

250. During the Class Period, Defendants used thousands of mail and interstate wire communications to create and manage their fraudulent scheme. Defendants' scheme involved national marketing and sales plans and programs, and encompassed physicians and victims across the country.

251. Defendants' use of the mails and wires to perpetrate their fraudulent scheme involved thousands of communications throughout the Class Period, including:

- marketing materials about the off-label uses of Neurontin, such materials being sent to doctors across the country;
- communications, including financial payments, between the vendor participants, physician participants, non-physician technical writers, and physician "authors" discussing and relating to the publication of articles touting off-label uses of Neurontin for which the drug is not safe and medically efficacious;
- communications, including financial payments, between the Defendants, the vendor participants and physician participants relating to the production of each and every event put on by the Off-Label Promotion Enterprise, including communications concerning the content of the presentations to be made at such events;
- teleconferences arranged by the Defendants and the participating vendors at which the participating physicians made false and misleading statements about Neurontin's use of unapproved indications to physicians, including but not limited to statements that Neurontin was effective for the treatment of off-label conditions;
- payments transported through the mail and the wires to physicians attending events held by the Off-Label Promotion Enterpise in order to induce the physicians to prescribe Neurontin notwithstanding fiduciary duties the physicians owed to their patients, physician practices, medical networks and others; and
- communications, payments and monetary transfers using the wires concening the receipt and distribution of the proceeds of Defendants' improper scheme.

252. In addition, Defendants' corporate headquarters have communicated by United States mail, telephone, and facsimile with various local district managers, medical liaisons and pharmaceutical representatives in furtherance of Defendants' schemes.

VIII. SCOPE OF THE ALLEGATIONS

A. Time

253. The conduct and patterns of conduct alleged herein, relating to the sale and marketing of Neurontin, occurred between December 30, 1993, the date that the FDA approved the marketing of Neurontin, and the present day. The Plaintiffs specifically allege that the conduct and patterns of conduct alleged herein occurred and continued to occur after the consummation of the merger between Pfizer, Inc. and Warner-Lambert Co. in June 2000.

B. Geographic Scope

254. The conduct and patterns of conduct alleged herein, relating to the sale and marketing of Neurontin, took place throughout the entire United States and District of Columbia, as well as various other territories and foreign countries. Although many of Defendants' sales and marketing strategies were executed through the Customer Business Unit ("CBU") system, a network of regional sales divisions that covered the entire country, those strategies were developed and disseminated by Defendants' Morris Plains, New Jersey headquarters.

IX. CLASS ACTION ALLEGATIONS

255. Under Rule 23 of the Federal Rules of Civil Procedure, Plaintiffs bring this action on behalf of themselves and a Class, defined as:

> All individuals and entities in the United States and its territories who, for purposes other than resale, purchased, reimbursed and/or paid for Neurontin for indications not approved by the FDA during the period from January 1, 1994, through the present. For purposes of the Class definition, individuals and entities

> "purchased" Neurontin if they paid some or all of the purchase price.

Excluded from the Class are (a) Defendants and any entity in which any Defendant has a controlling interest, and their legal representatives, officers, directors, assignees and successors, and (b) any co-conspirators. Also excluded from the class are any judge or justice to whom this action is assigned, together with any relative of such judge or justice within the third degree of relationship, and the spouse of any such person.

256. Additionally, Plaintiffs BCBSLA, Local 68, ASEA, and Harden bring this action on behalf of a Third Party Payer Subclass, defined as:

> All private, non-governmental entities in the United States and its territories that are at risk, pursuant to a contract, policy, or plan, to pay or reimburse all or part of the cost of Neurontin prescribed, provided, or administered to natural persons covered by such contract, policy, or plan for indications not approved by the FDA during the period from January 1, 1994 to the present. Such entities include, but are not limited to, insurance companies, union health and welfare benefit plans, entities with self-funded plans that contract with a health insurance company or other entity to serve as a third-party claims administrator to administer their prescription drug benefits, private entities paid by any governmental entity (including a state Medicaid program) to provide prescription drug benefits on a capitated basis, and other organizations that paid for all or part of a Neurontin prescription since January 1, 1994.

Excluded from this subclass are (a) Defendants and any entity in which any Defendant has a controlling interest, and their legal representatives, officers, directors, assignees and successors, and (b) any co-conspirators. Also excluded from this subclass are any individuals that belong to the Consumer Subclass, as defined below. Finally, also excluded from the class are any judge or justice to whom this action is assigned, together with any relative of such judge or justice within the third degree of relationship, and the spouse of any such person.

257. Additionally, plaintiffs Gerald Smith and Lorraine Kopa bring this action on behalf of a Consumer Subclass, defined as:

> All individuals in the United States and its territories who, for purposes other than resale, purchased, reimbursed, or paid for some or all of the price of Neurontin, for indications not approved by the FDA during the period from January 1, 1994 to the present.

Excluded from this subclass are (a) Defendants and any entity in which any Defendant has a controlling interest, and their legal representatives, officers, directors, assignees and successors, and (b) any co-conspirators. Also excluded from this subclass are any entities that belong to the Third Party Payer Subclass, as defined above. Finally, also excluded from the class are any judge or justice to whom this action is assigned, together with any relative of such judge or justice within the third degree of relationship, and the spouse of any such person.

258. The Class and Subclasses consists of numerous individuals and entities throughout the United States, making individual joinder impractical, in satisfaction of Rule 23(a)(1). The disposition of the claims of the Class and Subclass members in a single class action will provide substantial benefits to all parties and to the Court.

259. The claims of the representative Plaintiffs are typical of the claims of the Class and Subclasses, as required by Rule 23(a)(3), in that the representative Plaintiffs are persons who, like all Class members, purchased and/or paid for Neurontin for indications not approved by the FDA. Such representative Plaintiffs, like all Class Members, have been damaged by Defendants' misconduct, in that, among other things, they paid for Neurontin to treat a condition for which the drug had not been demonstrated to be medically effective or safe, and for which the drug was not FDA-approved.

260. The factual and legal bases of Defendants' misconduct are common to all members of the Class and Subclasses and represent a common thread of fraud and other misconduct resulting in injury to Plaintiffs and all members of the Class and Subclasses.

261. There are many questions of law and fact common to Plaintiffs, the Class, and the Subclasses, and those questions predominate over any questions that may affect individual Class members, within the meaning of Rule 23(a)(2) and 23(b)(3). Common questions of law and fact include, but are not limited to, the following:

- Whether Neurontin is medically necessary for uses not approved by the FDA;
- Whether Defendants engaged in a fraudulent and/or deceptive scheme of improperly marketing and selling Neurontin for conditions for which it is not safe or medically efficacious;
- Whether Defendants engaged in a fraudulent and/or deceptive scheme of improperly marketing and selling Neurontin to treat conditions for which the drug was not approved by the FDA;
- Whether Defendants coached or instructed physicians how to conceal the off-label nature of Neurontin prescriptions on claim forms submitted by or to Plaintiffs and members of the Class and Subclasses;
- Whether it was the policy and practice of Defendants to prepare, fund and publish materials which contained false information and misrepresentations regarding off-label uses for Neurontin;
- Whether Defendants paid non-physician technical writers to write articles containing misinformation and misrepresentations concerning purported scientific evidence regarding the safety and medical efficacy of Neurontin to treat off-label conditions;

- Whether Defendants paid physicians to "author" articles written by others containing misinformation and misrepresentations concerning purported scientific evidence to support the use of Neurontin for the treatment of conditions for which it has not been scientifically proven to be safe or medically effective;
- Whether Defendants paid Vendors, namely AMM and MES, to market articles containing misinformation and misrepresentations concerning purported scientific evidence regarding off-label uses of Neurontin for which the drug is not safe or medically necessary;
- Whether Defendants are liable to the Class Members and Subclass Members for damages for conduct actionable under the New Jersey Consumer Fraud Act;
- Whether Defendants are liable to Class Members and Subclass Members for damages for conduct actionable under the RICO statute;
- Whether Defendants are liable to Class Members and Subclass Members for damages for conduct actionable as common law fraud;
- Whether Defendants unjustly enriched themselves at the expense of Class Members and Subclass Members;
- Whether Defendants engaged in a pattern or practice that directly caused Plaintiffs, Class Members, and Subclass Members to pay for Neurontin prescriptions that were for non-medically necessary uses;
- Whether Defendants engaged in a pattern and practice that directly caused Plaintiffs, Class Members, and Subclass Members Class Members to pay for Neurontin prescriptions that were for non-FDA approved uses; and

- Whether Defendants engaged in a pattern of deceptive and/or fraudulent activity with the intent to defraud Plaintiffs, Class Members, and Subclass Members.

262. Plaintiffs will fairly and adequately represent and protect the interests of the Class and Subclasses, as required by Rule 23(a)(4). Plaintiffs have retained counsel with substantial experience in the prosecution of nationwide class actions. Plaintiffs and their counsel are committed to the vigorous prosecution of this action on behalf of the Class and Subclasses and have the financial resources to do so. Neither Plaintiffs nor counsel have any interests adverse to those of the Class or Subclasses.

263. Plaintiffs and members of the Class and Subclasses have suffered, and will continue to suffer, harm and damages as a result of Defendants' unlawful and wrongful conduct. A class action is superior to other available methods for the fair and efficient adjudication of the controversy under Rule 23(b)(3). Absent a class action, most members of the Class likely would find the cost of litigating their claims to be prohibitive, and will have no effective remedy at law. The class treatment of common questions of law and fact is also superior to multiple individual actions or piecemeal litigation in that it conserves the resources of the courts and the litigants, and promotes consistency and efficiency of adjudication.

FIRST CLAIM FOR RELIEF
VIOLATION OF 18 U.S.C. § 1962(C)

264. Plaintiffs incorporate by reference all preceding paragraphs as if fully set forth herein.

265. Defendants are "persons" within the meaning of 18 U.S.C. § 1961(3) who conducted the affairs of an enterprise through a pattern of racketeering activity in violation of 18 U.S.C. § 1962(c).

266. The Off-Label Promotion Enterprise is an association-in-fact within the meaning of 18 U.S.C. § 1961(4), consisting of each of Defendants, including their employees and agents, and the persons identified below. The Off-Label Promotion Enterprise is an ongoing organization that functions as a continuing unit. The Off-Label Promotion Enterprise was created and/or used as a tool to effectuate a pattern of racketeering activity. The Defendants are "persons" distinct from the Off-Label Promotion Enterprise.

267. Parke-Davis established the Off-Label Promotion Enterprise to accomplish two goals that were instrumental to its scheme to market Neurontin for off-label indications. First, it had to create parallel marketing structures that appeared independent from Parke-Davis's ordinary promotion forces to avoid federal regulations concerning off-label promotion. Second, to execute the publication strategy, favorable articles had to be generated and published that appeared to emanate from independent physicians. These two goals were complementary and mutually reinforcing. The production of favorable publications created a "buzz" regarding Neurontin, while the peer-to-peer marketing and promotion allowed aggressive sales pitches to continue with a veneer of legitimacy. To achieve these goals, two sub-enterprises were established: the Peer Selling Sub-Enterprise, described *infra*, and the Publication Sub-Enterprise, described *infra*.

268. Both sub-enterprises employed the same structure so as to avoid appearance of impropriety: the use of separate vendors who appeared independent and separate from Parke-Davis but over which Parke-Davis actually retained substantial control, coupled with the use of doctor-spokespersons as the mouthpiece for the Neurontin off-label message.

269. The common strategy employed by these sub-enterprises of recruitment and use of physicians, both for marketing and publication, created an explosion in the off-label

use of Neurontin by artificially creating the perception that independent physicians were studying and achieving favorable results with regard to off-label uses of Neurontin, and that physicians were clinically using Neurontin and investigating its efficacy in off-label uses on their own initiative. On the peer selling side, this objective was achieved through the peer-to-peer selling programs at medical education seminars, advisory boards, consultant meetings, speaker bureaus, and similar events that favorably discussed the off-label use of Neurontin. On the publication side, this objective was achieved by hiring non-physician technical writers to create the necessary articles, and then paid actual specialists to be the articles' "authors."

270. The participating vendors performed work that Parke-Davis could not appear to be doing, including funneling payments to physicians, misleading the public into believing the message was coming from a neutral source, and covering up Parke-Davis' control over the message of the Off-Label Promotion Enterprise. With regard to the Peer Selling Sub-enterprise, Parke-Davis recruited the physicians to deliver the Neurontin message and then provided this stable of physicians to participating vendors. Parke-Davis then funneled payments to these physicians through the participating vendors. Also, Parke-Davis paid for events hosted by the vendors at which these physicians would speak, where materially false information about Neurontin was given to attendee physicians. With regard to the Publication Sub-Enterprise, a similar strategy was employed: Parke-Davis decided what topics the papers would cover and paid all expenses. Then the vendors stepped in and provided technical writers to actually create the articles, after which a physician would be paid to lend his name to the article. Defendants' role in creating, approving, and paying for the articles was hidden from the public.

271. These systematic linkages between physicians, vendors, and Defendants all were established for a common purpose, to aid in marketing Neurontin for off-label uses.

Each of the participants—physicians, medical marketing firms, and publication vendors—received substantial revenue from the scheme to promote Neurontin off-label. Such revenue was exponentially greater than it would have been if Neurontin was marketed appropriately. All participants were aware of Defendants' control over the content of the presentations, speeches, promotional events, and articles that describe off-label usage of Neurontin and in the value of promoting Neurontin off-label. Furthermore, each portion of the enterprise benefited from the existence of other parts. For example, the Publication Sub-enterprise provided literature which lent an air of academic legitimacy and buttressed the claims being made by the off-label promotion sub-enterprise. And, on the other hand, the Peer Selling Sub-enterprise generated direct contacts with the physician community to spread the word regarding Neurontin, which provided the publication enterprise with greater interest in their work.

272. This common fraudulent purpose was effectuated through this broad network of Defendants, vendors and physicians. That network was held together by the funneling of funds through the vendors to the physicians, the content control by Parke-Davis and the use of participating vendors to spread that message, and a centralized decision-making process in which Parke-Davis made decisions about the marketing and promotion of Neurontin and controlled various third parties to make that happen.

273. Alternatively, the Off-Label Promotion Enterprise was and is comprised of the two large sub-enterprises, each of which is in and of itself an association-in-fact within the meaning of 18 U.S.C. § 1961(4). Those two sub-enterprises are the Peer Selling Sub-Enterprise and the Publication Sub-Enterprise. The Peer Selling Sub-Enterprise consists of Defendants, the vendor participants, and the participating physicians. The participating physicians include, but are not limited to, the 28 physicians identified, supra, in paragraph 96. The vendor participants

are Cline, Davis & Mann (and its Proworx division); Thompson Physicians World (and its Professional Postgraduate Services division); Sudler & Hennessy (and its Intramed division); MEDED/MEDCON; Medical Educational Services ("MES"); Healthcare Communications Group ("HCC"); CME, Inc.; and Baron LePore & Associates.

274. The second sub-enterprise, the Publication Sub-Enterprise, consists of Defendants, medical marketing companies, and participating physicians. The medical marketing companies are MES and AMM/Adelphi. These two sub-enterprises are each ongoing organizations that function as a continuing unit. Each sub-enterprise was created and/or used as a tool to effectuate Defendants' pattern of racketeering activity. Each sub-enterprise, by itself, could constitute a RICO enterprise. The Defendants are "persons" who are distinct from each of the sub-enterprises.

275. Furthermore, in the alternative, these two sub-enterprises could constitute RICO enterprises without the participating physicians. Each sub-enterprise could consist solely of the vendor participants and the Defendants. For the Publication Sub-Enterprise, it would be comprised of the medical marketing firms named above and Defendants. For the Peer Selling Sub-Enterprise, it would be made up of the vendors named above and Defendants.

276. Finally, in the alternative, these sub-enterprises can be broken down into further, smaller enterprises which were created and controlled by the Defendants for the purpose of promoting Neurontin for unapproved indications in contravention of the rules and regulatiosn regarding promotion of off-label pharmaceutical drugs. Each of these smaller entities is a RICO enterprise in and of itself. These smaller enterprises are comprised of one vendor participant in the Peer Selling Sub-Enterprise listed *supra*, or one medical marketing firm in the Publication Sub-Enterprise listed *supra*, along with Defendants, including their employees and agents, and

the participating physicians. For example, one such enterprise is comprised of Cline, Davis & Mann, Defendants, and the participating physicians. In the alternative, these smaller enterprises can also be comprised only of an individual vendor and Defendants, without the participating physicians.

277. The Off-Label Promotion Enterprise (and each of the sub-enterprises defined above) engaged in and affected interstate commerce, because, inter alia, it marketed, sold, purchased, or provided Neurontin to thousands of individuals throughout the United States.

278. Defendants have exerted control over the Off-Label Promotion Enterprise (and each of the sub-enterprises), and Defendants have participated in the operation or management of the affairs of the Off-Label Promotion Enterprise (and each of the sub-enterprises), through the following actions:

279. Defendants have asserted direct control over the information and content disseminated to the participating vendors, participating physicians, the physicians attending events presented by the Off-Label Promotion Enterprise and the public regarding the efficacy of Neurontin for off-label uses in events held across the country, in meetings between medical liaisons or participating physicians and target physicians and in articles published across the country;

280. Defendants have asserted direct control over the creation and distribution of marketing and sales materials sent to participating vendors, the participating physicians and the doctors attending events throughout the United States; and

281. Defendants have placed their own employees and agents in positions of authority and control in the Off-Label Promotion Enterprise (and each of the sub-enterprises).

282. Defendants have conducted and participated in the affairs of the Off-Label Promotion Enterprise (and each of the sub-enterprises) through a pattern of racketeering activity that includes acts indictable under 18 U.S.C. §§ 1341 (mail fraud), 1343 (wire fraud), 1952 (use of interstate facilities to conduct unlawful activity) and state bribery statutes, including, but not limited to N.J.S.A. 2C:21-10(b) as described above.

283. As detailed above, Defendants' pattern of racketeering activity includes acts indictable as mail fraud under 18 U.S.C. § 1341 and wire fraud under 18 U.S.C. § 1343. Defendants' fraudulent scheme consisted of, inter alia: (a) deliberately misrepresenting the uses for which Neurontin was safe and effective so that Plaintiffs and members of the Class paid for this drug to treat symptoms for which it was not scientifically proven to be safe and effective; (b) providing or publishing or causing to have provided or published presentations and materials containing false and/or misleading information upon which physicians, Plaintiffs, and members of the Class relied upon when choosing to prescribe or pay for Neurontin; (c) actively concealing, and causing others to conceal, information about the true safety and efficacy of Neurontin to treat conditions for which it had not been approved by the FDA; (d) intentionally misrepresenting and concealing Defendants' role and participation in the creation and sponsorship of a variety of events, articles and publications used to sell Neurontin to off-label markets; and (e) intentionally misrepresenting and concealing the financial ties between the Defendants and other participants in the Off-Label Promotion Enterprise.

284. In implementing their fraudulent scheme, Defendants were acutely aware that Plaintiffs and members of the Class depend on the honesty and integrity of Defendants in representing the medical efficacy of Neurontin's uses. It is impractical and unduly expensive for the Class Members to perform their own clinical trials or assemble all known medical evidence

relating to Neurontin's uses. The Class Members also rely on federal law obligating Defendants to provide fair and balance information about their drug products and reasonably presume that when such marketing of Neurontin was conducted, it complied with Defendants' obligations under federal law.

285. Defendants' scheme was calculated to ensure that Plaintiffs and the Class would pay for Neurontin to treat a wide variety of uses which Defendants knew were not necessarily treatable with Neurontin.

286. The Off-Label Promotion Enterprise used the mails and wire to implement the scheme. For example, the planning and coordination of events created by the medical marketing vendors required extensive use of the wire and mails, including the mailing of invitations to physicians, booking of hotels and airplane tickets, the arrangement of meals, the scheduling of teleconference calls, and the coordination of the content of the presentations on Neurontin to be presented at the event. Further instances of the use of mails and wires are contained supra at paragraphs 211-214.

287. As detailed above, Defendants' pattern of racketeering activity also includes acts indictable under state bribery statutes, including, but not limited to N.J.S.A. 2C:21-10(b) and 18 U.S.C. § 1952 (use of interstate facilities to conduct unlawful activity). Defendants' acts consisted of, inter alia: (a) paying substantial fees and extensive travel benefits to physician participants for agreeing to engage in peer-to-peer marketing; (b) paying physicians for studies that had minimal, if any scientific value or paying physicians to use their names on ghost-written articles; and (c) making outright payments, in the form of grants, to reward doctors who actively prescribed Neurontin or promoted it for off-label uses.

288. The Off-Label Promotion Enterprise also used interstate facilities, including the mails and wire, to violate state bribery statutes. For example, many of these payments to physicians involved use of mails and wire.

289. The conduct of the Off-Label Promotion Enterprise (and each of the sub-enterprises) described above constitutes "racketeering activity" within the meaning of 18 U.S.C. § 1961(1). Defendants' decision for the Off-Label Promotion Enterprise (and each of the sub-enterprises) to routinely conduct its transactions in such a manner constitutes a "pattern of racketeering activity" within the meaning of 18 U.S.C. § 1961(5).

290. The above described racketeering activities amounted to a common course of conduct intended to deceive and harm Plaintiffs and the Class. Each such racketeering activity was related, had similar purposes, involved the same or similar participants and methods of commission, and had similar results affecting similar victims, including Plaintiffs and the members of the Class. Defendants' racketeering activities are part of their ongoing business and constitute a continuing threat to the property of Plaintiffs and the Class.

291. Plaintiffs and members of the Class have been injured in their property by reason of these violations in that Plaintiffs and members of the Class have made billions of dollars in payments for Neurontin that they would not have made had Defendants not engaged in their pattern of racketeering activity.

292. Plaintiffs' and members of the Class' injuries were directly and proximately caused by Defendants' racketeering activity as described above.

293. By virtue of these violations of 18 U.S.C. § 1962(c), Defendants are jointly and severally liable to Plaintiffs and the Class for three times the damages Plaintiffs and the Class have sustained, plus the cost of this suit, including reasonable attorneys' fees.

SECOND CLAIM FOR RELIEF
VIOLATION OF 18 U.S.C. § 1962(D)
BY CONSPIRING TO VIOLATE 18 U.S.C. § 1962(C)

294. Plaintiffs incorporate by reference all preceding paragraphs as if fully set forth herein.

295. Section 1962(d) of RICO provides that it "shall be unlawful for any person to conspire to violate any of the provisions of subsection (a), (b) or (c) of this section."

296. Defendants have violated § 1962(d) by conspiring to violate 18 U.S.C. § 1962(c). The object of this conspiracy has been and is to conduct or participate in, directly or indirectly, the conduct of the affairs of the § 1962(c) Enterprises described previously through a pattern of racketeering activity.

297. As demonstrated in detail above, Defendants' co-conspirators have engaged in numerous overt and predicate fraudulent racketeering acts in furtherance of the conspiracy, including material misrepresentations and omissions designed to defraud Plaintiffs and the Class of money.

298. The nature of the above-described Defendants' co-conspirators' acts, material misrepresentations, and omissions in furtherance of the conspiracy gives rise to an inference that they not only agreed to the objective of an 18 U.S.C. § 1962(d) violation of RICO by conspiring to violate 18 U.S.C. § 1962(c), but they were aware that their ongoing fraudulent and extortionate acts have been and are part of an overall pattern of racketeering activity.

299. As a direct and proximate result of Defendants' overt acts and predicate acts in furtherance of violating 18 U.S.C. § 1962(d) by conspiring to violate 18 U.S.C. § 1962(c), Plaintiffs and the Class have been and are continuing to be injured in their business or property as set forth more fully above.

300. Defendants have sought to and have engaged in the commission of and continue to commit overt acts, including the following unlawful racketeering predicate acts:

a. Multiple instances of mail and wire fraud violations of 18 U.S.C. §§ 1341 and 1342;

b. Multiple instances of mail fraud violations of 18 U.S.C. §§ 1341 and 1346;

c. Multiple instances of wire fraud violations of 18 U.S.C. §§ 1343 and 1346;

d. Multiple instances of unlawful activity in violation of 18 U.S.C. §1952;

e. Multiple instances of bribery in violation of state statutes, including but not limited to N.J.S.A. 2C:21-10(a).

301. Defendants' violations of the above federal and state laws and the effects thereof detailed above are continuing and will continue. Plaintiffs and members of the Class have been injured in their property by reason of these violations in that Plaintiffs and members of the Class have made billions of dollars in payments for Neurontin that they would not have made had Defendants not conspired to violate 18 U.S.C. § 1962(c).

302. Plaintiffs' and members of the Class' injuries were directly and proximately caused by Defendants' racketeering activity as described above.

303. By virtue of these violations of 18 U.S.C. § 1962(d), Defendants are jointly and severally liable to Plaintiffs and the Class for three times the damages Plaintiffs and the Class have sustained, plus the cost of this suit, including reasonable attorneys' fees.

THIRD CLAIM FOR RELIEF
VIOLATIONS OF THE NEW JERSEY CONSUMER FRAUD ACT, N.J.S.A. 56:8-1 ET SEQ.

304. Plaintiffs incorporate by reference all preceding paragraphs as if fully set forth herein.

305. This claim is asserted by Plaintiffs on their own behalf and on behalf of all other similarly situated members of the Class against Defendants.

306. The unfair and deceptive acts and practices of Defendants have directly, foreseeable, and proximately caused or will cause damages and injury to Plaintiffs and the members of the Class.

307. The actions and failures to act of Defendants, including the false and misleading representations and omissions of material facts regarding the off-label use(s) for Neurontin, and the above described course of fraudulent conduct and fraudulent concealment, constitute acts, uses, or employment by Defendants of unconscionable commercial practices, deception, fraud, false pretenses, misrepresentations, and the knowing concealment, suppression or omission of material facts with the intent that others rely upon such concealment, suppression or omission of material facts in connection with the sale of merchandise of Defendants in violation of the New Jersey Consumer Fraud Act, N.J.S.A. 56:8-1, et seq.

308. Physicians relied upon Defendants' misrepresentations and omissions in prescribing Neurontin for "off-label" uses. As a direct and proximate result of Defedants' wrongful conduct, Plaintiffs and the Class were damaged by paying for these prescriptions.

309. As a direct and proximate result of Defendants' wrongful conduct, Plaintiffs and members of the Class are entitled to compensatory damages, treble damages, attorneys' fees and costs of suit.

FOURTH CLAIM FOR RELIEF
COMMON LAW FRAUD

310. Plaintiffs incorporate by reference all preceding paragraphs as if fully set forth herein.

311. This claim is asserted by Plaintiffs on their own behalf and on behalf of all other similarly situated members of the Class against Defendants.

312. Defendants made misrepresentations and omissions of facts material to Plaintiffs' and Class member's decisions to purchase Neurontin by, inter alia, (a) deliberately misrepresenting the uses for which Neurontin was safe and effective so that Plaintiffs and members of the Class paid for this drug to treat symptoms for which it was not scientifically proven to be safe and effective; (b) providing or publishing or causing to have provided or published presentations and materials containing false and/or misleading information upon which physicians, Plaintiffs, and members of the Class relied upon when choosing to prescribe or pay for Neurontin; and (c) actively concealing, and causing others to conceal, information about the true safety and efficacy of Neurontin to treat conditions for which it had not been approved by the FDA.

313. Defendants knew at the time that they made these misrepresentations that they were false or that Defendants had failed to disclose facts they were obligated to disclose in order to make their other representations not misleading. Defendants were aware that plaintiff's fiduciaries and agents, their physicians, would rely on these misrepresentations, and that such representations were material in the decision to prescribe or purchase Neurontin.

314. Plaintiffs and the Class reasonably relied upon Defendants' misrepresentations and omissions of material fact. Plaintiffs and the Class had no reason to

doubt the veracity or scientific validity of the information Defendants promoted through their marketing and sales strategies.

315. Defendants' misrepresentations and omissions of material fact directly and proximately caused Plaintiffs' and the Class' damages.

316. By virtue of the fraud they perpetrated on Plaintiffs and the Class, Defendants are jointly and severally liable to Plaintiffs and the Class for all damages Plaintiffs and the Class have sustained, plus punitive damages, plus the cost of this suit, including attorneys' fees.

FIFTH CLAIM FOR RELIEF
UNJUST ENRICHMENT

317. Plaintiffs incorporate by reference all preceding paragraphs as if fully set forth herein.

318. This claim is asserted by Plaintiffs on their own behalf and on behalf of all other similarly situated members of the Class against Defendants.

319. As the intended and expected result of their conscious wrongdoing as set forth in this Complaint, Defendants have profited and benefited from payments Plaintiffs and the Class made for Neurontin.

320. In exchange for the payments they made for Neurontin, and at the time they made these payments, Plaintiffs and the Class expected that the drug was a safe and medically effective treatment for the condition, illness, disease, disorder, or symptom for which it was prescribed.

321. Defendants have voluntarily accepted and retained these payments, with full knowledge and awareness that, as a result of their wrongdoing, Plaintiffs and the Class paid for Neurontin when they otherwise would not have done so. The failure of Defendants to

provide Plaintiffs and the Class with the remuneration they expected enriched Defendants unjustly.

322. Plaintiffs and the Class are entitled in equity to seek restitution of Defendants' wrongful profits, revenues and benefits to the extent, and in the amount, deemed appropriate by the Court; and such other relief as the Court deems just and proper to remedy Defendants' unjust enrichment.

DEMAND FOR RELIEF

WHEREFORE, Plaintiffs and the Class demand judgment against Defendants in each claim for relief, jointly and severally, as follows:

a. On Plaintiffs' and the Class' RICO claims, three times the damages Plaintiffs and the Class have sustained as a result of Defendants' conduct, such amount to be determined at trial, plus Plaintiffs' costs in this suit, including reasonable attorneys' fees;

b. On Plaintiffs' and the Class' New Jersey Consumer Fraud Act claim, compensatory damages, three times the damages Plaintiffs and the Class have sustained as a result of Defendants' conduct, such amount to be determined at trial, plus Plaintiffs' costs in this suit, including reasonable attorneys' fees;

c. On Plaintiffs' and the Class' common law fraud claim, compensatory damages, punitive damages, such amounts to be determined at trial, plus Plaintiffs' costs in this suit, including all reasonable attorneys' fees;

d. On Plaintiffs' and the Class' claim for unjust enrichment, recovery in the amount of Plaintiffs' and the Class' payment for Neurontin to treat conditions for which it was not approved by the FDA, such amount to be determined at trial, plus Plaintiffs' costs in this suit, including all reasonable attorneys' fees;

e. Awarding Plaintiffs and the Class other appropriate equitable relief;

f. Awarding Plaintiffs their costs and expenses in this litigation, including reasonable attorneys' fees and expert fees; and

g. Awarding Plaintiffs and the Class such other and further relief as may be just and proper under the circumstances.

DEMAND FOR JURY TRIAL

Pursuant to Federal Rule of Civil Procedure 38(b), Plaintiffs demand a trial by jury on all issues so triable.

Dated: February 1, 2005

Respectfully submitted,

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